



# Hygiene in food processing

Principles and practice

Second edition

Edited by H. L. M. Lelieveld, J. Holah and D. Napper





# **Hygiene in food processing**

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**H. L. M. Lelieveld, J. T. Holah and D. Napper**



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# Contributor contact details

(\* = main contact)

## Editors

Huub L. M. Lelieveld  
Formerly Unilever R&D  
Ensahlaan 11  
3723 HT Bilthoven  
The Netherlands

E-mail: huub.lelieveld@inter.nl.net

John T. Holah  
Campden BRI  
Station Road  
Chipping Campden GL55 6LD, UK

E-mail: john.holah@campdenbri  
.co.uk

David Napper  
Enviro-Development  
Vibevej 2  
6200 Aabenraa, Denmark

E-mail: dn@eseparator.com

## Chapter 1

Heidi Van de Weerd\*  
Strat-X bvba  
Grensstraat 85  
3140 Keerbergen  
Belgium

E-mail: Heidi.VdW@strat-x.be

Bernd van der Meulen  
Wageningen UR  
The Netherlands

E-mail: bernd.vandermeulen@  
wur.nl

## Chapter 2

Huub L. M. Lelieveld\*  
Formerly Unilever R&D  
Ensahlaan 11  
3723 HT Bilthoven  
The Netherlands

E-mail: huub.lelieveld@inter.nl.net

John T. Holah  
Campden BRI  
Station Road  
Chipping Campden GL55 6LD,  
UK

E-mail: john.holah@campdenbri  
.co.uk

### **Chapters 3, 9 and 16**

John T. Holah  
Campden BRI  
Station Road  
Chipping Campden GL55 6LD,  
UK

E-mail: john.holah@campdenbri  
.co.uk

### **Chapter 4**

Huub L. M. Lelieveld\*  
Formerly Unilever R&D  
Ensahlaan 11  
3723 HT Bilthoven  
The Netherlands

E-mail: huub.lelieveld@inter.nl.net

M. A. Mostert and G. J. Curiel  
Unilever R&D  
PO Box 114  
3130 AC Vlaardingen  
The Netherlands

### **Chapter 5**

Mike Lewan  
Materials Engineering Research  
Laboratory Ltd, UK

Eric Partington\*  
Nickel Institute, UK

E-mail: eric@effex.co.uk

### **Chapter 6**

Jürgen Hofmann\*  
Hygienic Design Weihenstephan &  
EHEDG, Germany

E-mail: jh@hd-experte.de

Timothy R. Rugh  
3-A Sanitary Standards, Inc.  
6888 Elm Street, Suite 2D  
McLean, VA 22101-3829, USA

E-mail: trugh@3-a.org

### **Chapter 7**

Keith L. Brown\*  
Formerly Campden BRI, UK

E-mail: keithbrown1948@hotmail  
.com

Stuart Wray  
Filtration Engineering UK Ltd  
Freudenberg Filtration  
Technologies

www.freudenberg-filter.com

### **Chapter 8**

Frank Moerman\*  
Catholic University of Leuven  
– KU Leuven  
Belgium

E-mail: fmoerman@telenet.be

S. Dewulf  
Dewulf Consulting, Belgium

E-mail: steven@filtration.be

## **Chapter 10**

Frank Moerman\*  
Catholic University of Leuven  
– KU Leuven  
Belgium

E-mail: fmoerman@telenet.be

P. Rizoulières  
Boccard Food, France

F. A. Majoor  
formerly Unilever R&D  
Vlaardingen  
The Netherlands

## **Chapter 11**

Frank Moerman\*  
Catholic University of Leuven  
– KU Leuven  
Belgium

E-mail: fmoerman@telenet.be

Piet Steenaard  
European Hygienic Engineering  
& Design Group  
Dr. Catzlaan 19  
NL-1261 CE Blaricum, The  
Netherlands

E-mail: steenaard@kpnmail.nl

John T. Holah  
Campden BRI  
Station Road  
Chipping Campden GL55 6LD,  
UK

E-mail: john.holah@campdenbri  
.co.uk

## **Chapter 12**

Edyta Margas\*  
Bühler AG  
Corporate Technology  
CH-9240 Uzwil, Switzerland

E-mail: edyta.margas@gmail.com

John T. Holah  
Campden BRI  
Station Road  
Chipping Campden GL55 6LD,  
UK

E-mail: john.holah@campdenbri  
.co.uk

## **Chapter 13**

Mike Edwards  
Campden BRI  
Station Road  
Chipping Campden GL55 6LD,  
U.K.

E-mail: mike.edwards@campdenbri  
.co.uk

## **Chapter 14**

Loek Kloosterman\*  
Optascan, The Netherlands  
Kooisloot 14  
8538 RD Bantega

E-mail: l.kloosterman@optascan.nl

Karel Mager  
EHEDG, The Netherlands

E-mail: karel.mager@gmail.com

### **Chapter 15**

Christopher H. Bell  
Food and Environment Research  
Agency  
70 Strensall Road  
Huntington  
York YO32 9SH, UK

E-mail: [chris.bell@fera.gsi.gov.uk](mailto:chris.bell@fera.gsi.gov.uk);  
[candv@bellhuntington.fsnet](mailto:candv@bellhuntington.fsnet.co.uk)  
.co.uk

### **Chapter 17**

Hein Timmerman  
Diversey  
Sealed Air Corporation, USA  
and  
European Hygienic Engineering &  
Design Group (EHEDG),  
Belgium

E-mail: [hein.timmerman@sealedair](mailto:hein.timmerman@sealedair.com)  
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# Introduction

**H. L. M. Lelieveld, formerly Unilever, The Netherlands**

It is a pleasure to know that the first edition of this book, published in 2003, is still very much in demand. After many reprints, the publisher and editors agreed that it was time to develop a second edition. Although the principles of hygienic processing are still the same, in the past 10 years much has happened that has justified a thorough update of the book. Application of the principles of hygienic processing has clearly increased, as witnessed by the increase in hygienically designed processing facilities and equipment that are now offered. However, the lack of application by some companies has regrettably contributed to continued food safety incidents, often with dramatic and fatal consequences. That these incidents continue to occur despite the wealth of available literature on the subject, including Woodhead Publishing's *Handbook of hygiene control in the food industry* and *Hygienic design of food factories* as well as more than 40 guidelines (all available in several languages) on hygienic design produced by EHEDG, shows that there is still insufficient awareness of what may go wrong during processing and how to prevent this.

This new edition has been revised to include more, and more detailed, information as well as information that was lacking in the first edition. Some chapters have been combined where this seemed more logical and some chapters have been completely overhauled to be able to incorporate more details to facilitate application of the information presented. The chapter on 'Sources of contamination' has been expanded to include a discussion of hazards and risk reduction by controlling vectors of contamination. The chapter on 'Hygienic plant design' has been completely renewed and covers not only the structure of the building, but also issues such as site selection, the many different areas in a food factory (high care/high risk; storage;

personnel) and how they should or should not be interconnected to avoid cross-contamination. In addition, the developments that have taken place since the first edition of this book in terms of methods to measure cleanliness of open and closed equipment have made it necessary to completely renew the chapter 'Verification and certification of hygienic design in food processing'.

The first edition of the book lacked a chapter on the control of compressed gases, used either in the product or to pneumatically operate equipment. An extensive chapter has now been added covering the production and control, potential contaminants and their removal, control of moisture and oil, monitoring and maintenance and safety aspects. The chapter 'Cleaning in place' has been expanded to include more detailed information, allowing the reader to design more cost-effective CIP systems. The chapter pays also considerable attention to more effective and efficient cleaning of tanks showing how cleaning times can be reduced. Also new is the chapter on maintenance of equipment, essential to prevent the development of contamination risks that were not there when the plant was new. Although the first edition included a chapter on pest control, it lacked an introduction to the problems of controlling pests in the food industry. A further chapter on this topic has now been added.

The final part of the book includes a new chapter on 'Microbiological environmental sampling', which is used to estimate the risk of contamination of the product by microbes in the immediate environment of the product. The final chapter in the book covers the economics and management of hygiene in food plants. This chapter is important, because it demonstrates that paying adequate attention to hygiene in food processing avoids undue expenses and unexpected costly problems. The chapter discusses the real costs of hygiene, split into direct (materials, labour, energy) and indirect factors.

Food plant managers, suppliers of food processing equipment and building contractors should find within this book much of the information they and their staff need to enable the production of safe food. Where more details are required, the lists of references and sources of further information will indicate where to find such information. Food inspectors, often not familiar with design aspects of food factories, will find it fairly easy to find answers to their questions. For further information, the EHEDG website ([www.ehedg.org](http://www.ehedg.org)) is continually updated and EHEDG can always be contacted for further discussion.

# 1

## Food hygiene regulation in the European Union (EU)

**B. Van der Meulen, Wageningen UR, The Netherlands and  
H. Van de Weerd, Strat-X bvba, Belgium**

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**Abstract:** The nature and application of the regulatory regime in the EU are described and the structure of the control system is covered before examining the EU legal requirements. There is further discussion on the legislation applicable to retailing and catering for all foods, and to the whole supply chain for many foods. The specific requirements applicable to the production of foods of animal origin on an industrial scale and the rules and controls smaller businesses have to comply with are also discussed. The chapter then considers future trends before concluding with a list of sources of further information.

**Key words:** hygiene regulation, legislation, food business operators, HACCP.

### 1.1 Introduction

European law attaches prime importance to the safety of food products. To live up to this requirement, the food industry needs to apply quality management systems. The industry is achieving this. Independent auditing of these systems to demonstrate their performance is becoming increasingly common. Also, retail organizations are more and more demanding on this: for producers of their private labels, they have developed standards which need to be fulfilled by their suppliers before they are allowed to supply private label products. In this way compliance with legal obligations and sometimes more than the legal obligations becomes a contractual obligation as well (Van der Meulen 2011). Appropriate hygiene must be applied as necessary during all stages preceding the consumption of food to ensure that it is safe. It is apparent that this, and improved public awareness of it, are fundamental to the maintenance of consumer confidence. It also aids business profitability by reducing losses.

## 4 Hygiene in food processing

There must be an adequately equipped and controlled environment and appropriate hygiene procedures for the production, handling, storage, distribution and supply of food ingredients, packaging materials and foods. This may be based on detailed prescriptive controls providing a rigid guarantee of safe working, or a more flexible management system based on the control of objectively assessed risk, or a combination of these. In each case, implementation must be under the control of food business operators, who are responsible for ensuring that the products they supply are safe. A regulatory regime with effective enforcement is also necessary to deal with residual errors, failures and especially abuses.

This chapter discusses the nature and application of this regime in the EU. It covers the structure of the control system before examining the EU legal requirements. There is legislation generally applicable to retailing and catering for all foods, and to the whole supply chain for many foods. Although there are specific requirements applicable only to the production of foods of animal origin on an industrial scale, smaller businesses also have to comply with rules and controls. The chapter then considers future trends before providing a short list of sources of further information.

### 1.2 History of hygiene regulation in the European Union (EU)

In the 1960s legislation in the EU (at that time known as the European Economic Community, EEC) was mostly targeted to prevent outbreaks of animal diseases, such as bovine tuberculosis and foot-and-mouth disease. In the meantime there was also an international evolution: in 1963, the Codex Alimentarius was set up. This was done jointly by United Nations Food and Agriculture Organization and the World Health Organization. The aim of this was to protect consumers' health and to ensure fair practices in the international trade of food by developing common food safety standards. To this day, Codex Alimentarius is *the* reference for food safety systems and standards.

During this time, there has also been more industrialization of the food chain where food has become more centrally prepared and pre-packed. As such, the time between preparing and consuming of food has increased so that unwanted bacteria (spoilage) and other harmful organisms (pathogens) can potentially develop.

The first EU food hygiene rules, developed in 1964, were limited to requirements for fresh meat. Over the decades, this has expanded to other food from animal origin.

In the 1990s, a set of directives on food hygiene were published which was required to be translated into member states' national legislation. The base of this was The General Food Hygiene Directive (93/43/EEC) (EC 1993).

An important milestone in European food legislation was the publication of the Commission's White Paper on Food Safety in 2000 (EC 2000). In this paper, the approach for a reform of EU food legislation was developed. The main principles were defined:

- The rules should apply 'from farm to fork', which has as the result that every single step in the food production chain was covered by EU food safety legislation.
- Each food operator is responsible for the food safety of every food, imported, produced, processed or placed on the market. The member states and their competent authorities are in charge of verifying the correct application of the European legislation on food safety and its implementation. The philosophy is not to place hazardous products on the market and intervene when it is considered that a non-compliant product has been placed on the market.
- The products are to be traceable at every stage of the food chain.
- Legislation needs to be based on risk analysis, where the precautionary principle will be applied.

This White Paper resulted in the current European food safety legislation.

### **1.3 Key elements of hygiene regulation in the EU**

#### **1.3.1 Directives versus regulations**

In the past, European food legislation was mostly defined in directives. The nature of EU directives is that they address member states and have to be implemented through national legislation. Each member state must introduce its own measures to implement each directive within a specified period to achieve the objectives agreed and set out in the directive.

Since the publication of the White Paper, the choice has been made to define EU food legislation in regulations which apply automatically. This has had the result that the lines are more clear and uniform over the different countries. Nevertheless, within the limits set by the regulations it is still possible for individual countries to define national legislation.

#### **1.3.2 Horizontal versus vertical control measures**

The European food legislation consists of horizontal and vertical measures: horizontal legislation is generally applicable to all food business operators, and vertical legislation is applicable for specific sectors/products.

#### **1.3.3 Structure of the hygiene regulation**

The basis of hygiene regulation and other food law is laid down in the General Food Law (Regulation (EC) 178/2002 'GFL'; EC 2002). In Article

14 GFL it is defined that ‘Food shall not be placed on the market when it is unsafe’. Based on this, a so-called hygiene package has been developed. The three most important regulations in this package (sometimes referred to as H1/H2/H3) are:

- Regulation (EC) 852/2004 (EC 2004a) on the hygiene of foodstuffs
- Regulation (EC) 853/2004 (EC 2004b) laying down specific hygiene rules for food of animal origin
- Regulation (EC) 854/2004 (EC 2004c) laying down specific rules for the organization of official controls on products of animal origin intended for human consumption.

Article 2 of the horizontal Regulation on the hygiene of foodstuffs (852/2004) defines ‘food hygiene’ as ‘the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use’. This means that hygiene is necessary to fulfil Article 14 of the general food law.

In general, four groups of hazards which can cause unsafe food are identified:

- microbiological hazards
- physical hazards
- chemical hazards
- allergen hazards.

For control of these hazards, there is also defined EU legislation. An overview of this is given in Table 1.1.

## 1.4 Content of the hygiene regulations

### 1.4.1 General food law (Regulation (EC) 178/2002)

The general food law (EC 2002) provides the framework in which all food legislation is embedded. The aim of the general food law is to protect public health and consumers’ interest in relation to food. The regulation applies to all stages of production, processing and distribution of food and feed with the exception of domestic activities. In addition, this regulation also defines the structure and tasks of the European Food Safety Authority (EFSA).

The general food law defines several core concepts of food law. In the other food legislation, reference is often made to these definitions. See for example Article 2(2) of Regulation (EC) 852/2004 (EC 2004a). The general food law also provides general principles of food law, such as:

- Food law shall be based on risk analysis where possible.
- Precautionary principle: Where after risk an uncertainty persists, provisional risk management measures may be taken to ensure a

**Table 1.1** Overview of the structure of EU legislation

H1/H2/H3 (EC 852/2004 – EC 853/2004 – EC 854/2004) (EC 2004a–c)						
Microbiological hazards	Chemical hazards	Physical hazards	Allergens	Additives	Contact materials	Equipment
EC 2073/2005	EC 1881/2006 (EC 2006b)	FDA	EC 1169/2011 (EC 2011b)	2008/128/EC (EC 2008b)	EC 1935/2004 (EC 2004d)	2006/42/EC (EC 2006a)
Water quality (regional)	EC 396/2005 (EC 2005)			2008/60/EC (EC 2008a)	EC 450/2009	
	EC 37/2010 (EC 2010)			EC 1331/2008 (EC 2008c)	EC 2023/2006 (EC 2006b)	
				EC 1332/2008 (EC 2008d)	EC 10/2011 (EC 2011a)	
				EC 1333/2008 (EC 2008e)		
				EC 1334/2008 (EC 2008f)		
				95/2/EC (EC 1995)		

## 8 Hygiene in food processing

high level of health protection, until more scientific information is available.

- Consumers' interests will be protected.

To attain this, the most important principle is that there will be no food placed on the market which is unsafe. All food operators are responsible for their part of the food chain to achieve this. This is also the reason why traceability in the food chain is so important. All food and feed business operators need to have a system in place in which they can trace their products (Article 18 GFL). This system needs to cover the incoming ingredients (product, date of delivery/batch code and from which supplier), the outgoing products (products, dates of delivery and batch codes and to which customer) and – although the law does not explicitly state this – ideally also the link between the end products and raw materials. In essence, this means that businesses must assure the traceability from one step back in the food chain to one step forward. The burden to reconstruct the entire chain in case of an incident is on the authorities. In practice, the business operator also needs to identify where in the process batches are mixed or traceability is less accurate. This can be the case, for example, in silos which are not completely emptied before a new delivery arrives. The grade of (in) accuracy needs to be identified so the operator knows how to handle this in case of incidents. After all, it is the responsibility of food business operators to withdraw products that they have placed on the market that they believe are not in compliance with the food safety requirements. When they believe there are such products on the market, they also have to notify the competent authorities (Article 19 GFL). If circumstances so require, this may be communicated via the Rapid Alert System (Article 50–53 GFL).

### **1.4.2 Hygiene package H1/H2/H3 (EC 852/2004 – EC 853/2004 – EC 854/2004)**

The base legislation is Regulation (EC) 852/2004 (EC 2004a), which lays down the general requirements on food hygiene. The scope of this regulation covers all food business operators, being 'the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control' (Article 3(3) GFL), with the exception of domestic use.

Detailed obligations for the food business operators (FBOs) are defined in the annexes to this legislation. These requirements imply that good manufacturing practices (GMPs) are implemented. They can also be fulfilled through pre-requisite programmes, e.g. as described in 'retailer' standards, such as the British Retail Consortium Global Food Standard (BRC, 2011), IFS (2006), but also ISO 22000 (ISO, 2005).

In Annex 2, requirements concerning the FBOs are defined. The specific requirements depend on the type of activity: there are general requirements,



which apply for all food premises, requirements for rooms where foodstuffs are prepared, treated or processed, requirements for movable and/or temporary premises and requirements for transportation. The requirements can be grouped as follows:

- Food premises, which include requirements concerning layout, design, construction, siting and size of the premises, including sanitary facilities, ventilation, lighting, drainage, changing facilities, storage of cleaning agents and disinfectants.
- Equipment requirements including specific requirements for the materials which come in contact with the food products, cleaning and disinfection of the equipment, construction and installation.
- Food waste, where an important requirement is that the waste needs to be taken out of the production area as soon as possible, avoidance of accumulation of waste, deposition in closable containers, storage of waste and elimination of waste.
- Water supply, in which the use of potable water is required, with exceptions for the use of:
  - clean water for whole fishery products,
  - non-potable water for fire control, steam production, refrigeration and other similar purposes, in case this is kept in a separated, clearly identified system,
  - recycled water in processing.

Ice and steam also need to be of a quality which does not give a risk for contamination of the product. The definition of the parameters for potable water is a regional responsibility, as well as the required analyses on this.

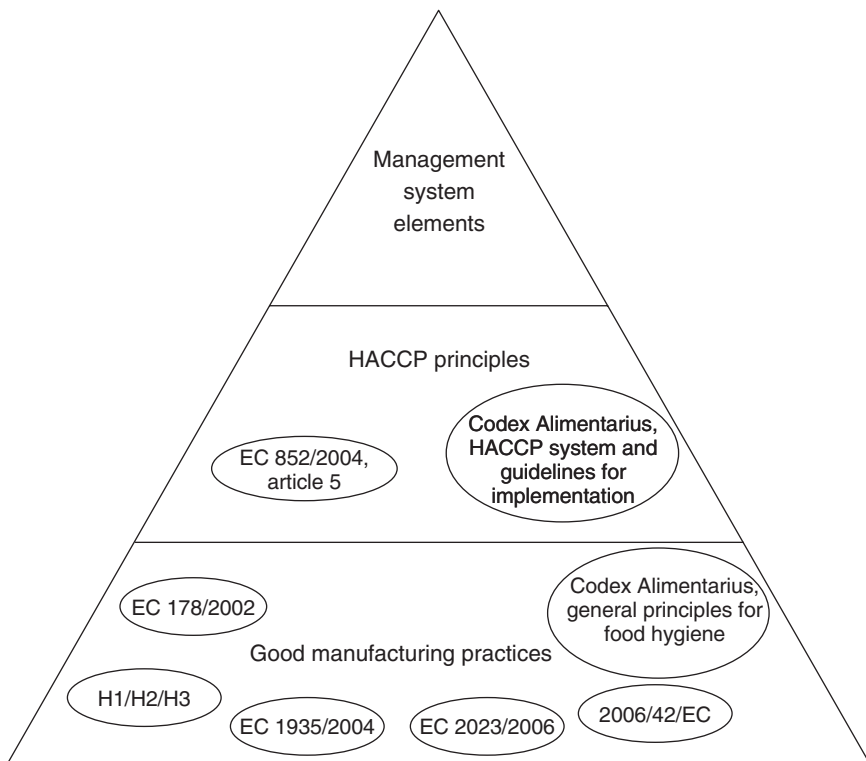
- Personal hygiene in which the requirements for suitable clothing and the freedom from diseases or infected wounds for food handlers are highlighted.
- Provisions for foodstuffs including the requirements to use suitable raw materials and ingredients. Also storage is an important part of this chapter. Temperature control, thawing procedure, identification and pest control are logical requirements with regard to the storage of the products.
- Wrapping and packaging of foodstuffs may not cause a risk of contamination. This means that the materials need to be stored in a way they are not exposed to the risk of contamination. The wrapping and packaging operations are carried out in an appropriate way and reusable materials need to be easy to clean and, where necessary, disinfected.
- For heat treated foods in hermetically sealed containers, it is required that the heat treatment (time and temperature) are controlled and that the product is prevented from contamination during that process. To control the heat treatment process, the relevant parameters need to be

verified regularly. The defined time and temperature should conform to internationally recognised standards.

- Training of food handlers is necessary. This can mean supervision of the food handlers, instruction and/or training. It is important that a certain minimum degree of training concerning hygiene and other instructions are given before the start of their activities. Training of the employees, responsible for the development of a hazard analysis system, usually adopted as the hazard analysis critical control point (HACCP) system is also a necessity.

These requirements are in fact the base from which to start as a food operator. As illustrated in Fig. 1.1 GMPs are the base of the triangle.

Next to the GMPs, Regulation (EC) 852/2004 (EC 2004a) requires FBOs to put a system in place, based on the HACCP principles (article 5). More information about this can be found in Section 1.5. Regulation (EC) 853/2004 (EC 2004b) which specifically targets FBOs handling food of animal origin. Rules, supplementary to Regulation 852/2004, are laid down.



**Fig. 1.1** Structure of a food safety management system (FSMS) Bernd van der Meulen and Heidi van der Weerd, Wageningen UR, The Netherlands.

Most of the rules are applicable to food products containing only animal products, not to food containing both products of plant origin and processed products of animal origin.

The FBOs which place products of animal origin on the market need to be registered or approved by the competent authority in the member states. The approval requirement applies to all FBOs except for primary production, transport, storage of products which do not need temperature controlled storage and retail operators.

Products of animal origin placed on the market must have a health or identification mark on the label. An FBO may only apply an identification mark on a product when the product has been manufactured in their facilities and they may not remove the health or identification mark. The identification mark needs to be applied before the product leaves the production establishment. It is not allowed that the mark is put on the product later, e.g. by a service provider who labels the products. If the original mark is removed because the product is further processed in another establishment, a new mark must be applied, but this must indicate the approval number of the establishment where the further processing takes place. In accordance with Regulation (EC) 178/2002 (EC 2002), the food business operators must have systems in place to identify the FBOs from whom they have received the products. So the original identification mark may be removed from the product, but it still is necessary to be able to trace it.

The format of the mark is clearly defined. The mark is oval in shape and must indicate the country as well as the approval number of the establishment.

Specific requirements are defined for importing products of animal origin from third countries. The combination of the product and the country needs to be allowed by the EU and the product must conform to the requirements of the EU.

Regulation (EC) 853/2004 (EC 2004b) clearly defines the names of the products of animal origin. This is done in Annex I. These definitions are important for the naming of the products, but also for storage conditions, etc., which are defined in this legislation. For example the definition of minced meat is boned meat that has been minced into fragments and contains less than 1% salt. Above this salt level, with regard to this legislation, the food is not seen as 'minced meat', but as a 'meat preparation'. This is important with regard to several requirements, such as storage temperature of the products, because 'minced meat' needs to be stored at maximum of 2 °C and 'meat preparations' at a maximum of 4 °C (Annex 3). This means that the limit of 1% salt is very important.

This regulation also contains specific GMP requirements for the different types of establishments which produce or process food products from animal origin. These are on top of the requirements defined in Regulation (EC) 852/2004 (EC 2004a), which lays down the rules concerning the official controls on products of animal origins. This is, in fact, a regulation which

defines how Regulation 853/2004 will be enforced by the competent authorities.

This regulation defines the approval of establishments demanded in Regulation 853/2004 as well as the general principles for the official controls of products of animal origin.

## **1.5 Hazard analysis critical control point (HACCP)**

In Regulations (EC) 852/2004 (EC 2004a) and (EC) 853/2004 (EC 2004b), there is a requirement for a hazard analysis system usually based on HACCP principles. HACCP is defined by the Codex Alimentarius and consists of seven principles. The principles are also included in Article 5(2) of Regulation (EC) 852/2004. Here they are phrased as follows:

- (a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
- (b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;
- (c) establishing critical limits at critical control points (CCPs) which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
- (d) establishing and implementing effective monitoring procedures at CCPs;
- (e) establishing corrective actions when monitoring indicates that a CCP is not under control;
- (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively.

To develop a practical HACCP system, the Codex Alimentarius (1997b) suggests 12 steps (Annex to CAC/RCP 1-1969). In Table 1.2 the relation between the two is taken. Looking at this table, it becomes clear that the 12 steps contain all seven principles, but also have some ‘preliminary steps’ as they are called in ISO 22000:2005 (ISO 2005).

### **1.5.1 HACCP team and definition scope (step 1)**

The first step is the definition of the HACCP team and the scope of the HACCP study. The HACCP team needs to be a team with multi-disciplinary knowledge. People with different backgrounds need to take part in the HACCP team and the team is likely to include knowledge of processes, products, customer requirements, microbiology, chemical hazards, equipment, etc. In addition to that, members of the HACCP team should

**Table 1.2** Seven principles and twelve steps of HACCP and their relation

Seven principles	Twelve steps
	The HACCP team & definition of the scope
	Product description
	Intended use
	Flow diagram
	Verification flow diagram
Hazard identification, analysis and control	Hazard identification, analysis and control
Determination of the CCPs	Determination of the CCPs
Establishing critical limits	Establishing critical limits
Monitoring CCPs	Monitoring CCPs
Corrective action plan	Corrective action plan
Verification of the HACCP system	Verification of the HACCP system
Record keeping	Record keeping

also have experience of/be trained in the principles of developing and implementing a FSMS.

It is very important that the HACCP team has the commitment of the senior management. It is possible that during the HACCP study it becomes clear that investments need to be done. If there is no senior management commitment, such investment may not be undertaken and the system will not be effective. Commitment is not as such required in EU law (just compliance). Several retailer standards, however, do hold requirements to this effect.

The scope needs to be defined very clearly:

- Which products are in the scope?
- What processes are used to produce these products?
- Who are the customers?
- What is the market?
- What are the demands concerning the products?
- Which are the applicable legislations?

### 1.5.2 Product description (step 2)

The products have to be described in detail. Products are not only the end products and raw materials, but also processing aids and food contact materials.

For the different products, the different characteristics need to be described (biological, chemical, physical, allergens, composition, method of production, packaging and delivery, storage and shelf-life, acceptance criteria, relevant legislation).

### **1.5.3 Intended use (step 3)**

It is important to describe the intended use of the products; this includes the user groups (young, old, pregnant, infant), but also limitations of use and possible misuse. It is possible that contact materials are suitable for contact with watery products, but not for fat products, so they cannot be used for chocolate, for example. The normal use also needs to be defined: this can be the preparation methods, storage conditions, shelf-life, etc.

### **1.5.4 Process description and flow diagram (step 4)**

The sequence and interaction of the different process steps need to be identified including: outsourced processes, where the products enter the flow, rework, recycling, removal of end products, intermediate products, by-products, waste, intermediate storage, water use, but also where the risks are for contamination, whether there are crossing flows, contact of cooked products with raw materials, etc.

This is primarily done by means of a flow chart, which gives a schematic view of the process, in combination with a layout of the site, on which the different flows (materials, waste, people) are drawn.

### **1.5.5 Process description and flow diagram (step 5)**

To be certain that the process description and the flow diagrams are correct, it is important that they are verified, in practice, but also in different production scenarios. This means in the different shifts (weekend, night, seasonal activities), as well as for the different stages of the process (e.g. cleaning in place, CIP).

Where necessary, the process description and/or flow diagrams need to be adapted.

### **1.5.6 Hazard identification, analysis and control (step 6, principle 1)**

To be able to undertake a thorough good hazard identification, it is important to know what the product is, the process, the use, and so on of the product (as defined in the previous steps). Based on that, possible hazards can be identified. These hazards can be from different types:

- microbiological hazards;
- physical hazards;
- chemical hazards;
- allergen hazards

For each hazard that has been identified (and this does not mean generic hazards such as ‘chemical contamination’, but specific hazards, such as lubricants at specific places, chemicals coming from specific contact materials, etc.), the risk, based on the occurrence of the hazard (how many

times can this hazard occur), and the severity (what the effect will be if this hazard occurs) need to be assessed.

The severity should be defined for each type of hazard (possibly depending on the stage in the process if the hazard is eliminated somewhere in the process, such as foreign materials which are eliminated by a filter somewhere in the process). The occurrence depends on the process step which is evaluated.

### 1.5.7 Determination of the CCPs (step 7, principle 2)

An evaluation of the hazards may lead to the designation of some hazard control steps as CCPs. The definition of a CCP is 'a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level'.

The question which needs to be asked is whether it is essential to eliminate the hazard or reduce it to acceptable levels. For this, a logical approach is necessary. This approach should be based on the occurrence of the hazard and the severity of the effect on consumer safety. This can be used as such, or combined with a decision tree, or only a decision tree can be used. An example of a matrix which can be used for the determination of CCPs is shown in Table 1.3. To define the risk, a combination of the occurrence of the hazard and the effect of that hazard is taken. In this case, when the risk number, which is the occurrence multiplied by the effect of the hazard, is more than 4, mostly this risk is a CCP or a point of attention.

This means that a very serious risk, which can lead, for instance, to life-threatening situations or diseases, but which has a very small occurrence can be nevertheless a CCP for a company. On the other hand, a risk which has a very limited effect, for instance, a hazard which only gives some discomfort, but has a daily occurrence, also needs to be controlled in the HACCP system.

If there are steps further in the process that take away this hazard, it can be taken that it is not a CCP or point of attention.

**Table 1.3** Example of a matrix to be used for the determination of CCPs

Occurrence				
Big (5)	5	10	15	25
Real (3)	3	6	9	15
Small (2)	2	4	6	10
Very small (1)	1	2	3	5
	Very limited (1)	Intermediate (2)	Serious (3)	Very serious (5)
		Effect		

### **1.5.8 Establishing critical limits (step 8, principle 3)**

For each CCP a critical limit needs to be defined. A critical limit is the criterion which separates acceptability from unacceptability. The critical limit is the moment where it is not sure that the product is safe, or where the product is potentially unsafe. This limit needs to be based on something such as literature, science, testing.

It is advised to make sure a critical limit is measurable. In these cases there is a clearly defined black/white situation. When a critical limit is based on subjective data (e.g. colour, visual inspection) it is important that this is clearly documented and the employees are trained.

### **1.5.9 Monitoring CCPs (step 9, principle 4)**

Once the CCPs and the critical limits are defined, methods for their monitoring can be developed. This can be simple, such as the measurement of the temperature of a refrigerator, but can also be more complex. It is, for instance, possible that the critical limit is that the product needs to be sterilized at a certain sterilization value, but that the temperature and the flow of the product is measured. In these cases the link between the critical limit and the measurement needs to be defined and calculated. It needs to be clear and certain that the monitoring guarantees that the critical limit has been met.

To develop the monitoring method the following items need to be defined:

- measurement taken for the monitoring (temperature, time, humidity)
- frequency of measurement (continuous, every hour, every shift)
- equipment used
- who is responsible for the measurement
- where and how is this recorded
- user training.

### **1.5.10 Corrective action plan (step 10, principle 5)**

In the case that a critical limit is exceeded, the corrective action needs to be defined. Corrective actions must include actions to return the process to its normal operating parameters and actions to ensure the safety of any food products manufactured during the time the process was non-compliant.

These corrective actions can be manual, but also can be defined within the software of the equipment. A common example of this is circulation of a liquid (e.g. milk) in a pasteurizer or sterilizer when the temperature is not sufficient. In these cases it is important that these systems are verified as part of the control of the CCP (does the product circulate at the expected temperature?). Responsibilities for the corrective actions need to be defined.



**1.5.11 Verification of the HACCP system (step 11, principle 6)**

To verify the HACCP system, there are three questions which need to be asked:

- Is the system up to date?
- Is the system implemented?
- Is the system effective?

To be able to answer the first question, it is important to make sure the preliminary steps of the HACCP study are up to date. Therefore, it needs to be verified if there have been any changes in the process, if there are new processes developed, if there are new products, raw materials, changes in the recipes or changes in legislation etc.

To verify if the system is implemented, it is important to check if the CCPs are monitored as defined: Are they monitored? Are the critical limits respected in cases where there was a deviation in the critical limit? Was the defined corrective action taken? Did the responsible employees take the decisions as defined? These checks need to be done for each CCP. In addition, the results of internal audits can be used as part of the verification of the implementation of the system.

To verify if the system is effective, several sources of information can be used, such as customer complaints, internal non-conformities, analyses of products or intermediates, etc.

**1.5.12 Record keeping (step 12, principle 7)**

To make it possible to verify the system and to prove that the system is working, all steps of the HACCP should be recorded.

**1.6 European hygiene legislation with regard to equipment****1.6.1 Design of equipment for the food industry (Directive 2006/42/EC)**

In Directive 2006/42/EC (EC 2006a), supplementary requirements are taken for certain categories of machinery, including foodstuffs machinery. In the design of machinery for foodstuffs, it is important that the surfaces which come in contact with the food products do not give any risk of contamination to the product. The risk of contamination can be physical (loose parts of machinery entering into the food products), chemical (by migration of unsuitable food contact materials) and microbiological (when the machine is not easy to clean, allowing microbial harborage and potential growth).

Where water is used during processing, which can be the case in the processing of vegetables needing to be washed, or during cleaning, the machines need to be designed in such a way that fluids are not flowing

across the floor, but immediately into the drains. Cleaning and rinsing fluids need to be discharged completely from the machinery.

Infestation with pests, specifically insects, should be prevented. This can be achieved by preventing pest entrance into the machines, but also by preventing product harborage sites and ease of access for thorough cleaning. Examples of this types of contamination are cocoa moths and flour moths, but also cockroaches, which like to be in dark, warm places.

Food contact points with lubricants need to be eliminated and where there is still a possibility for incidental contact, the lubricants need to be food grade. Finally, the methods and products for cleaning and disinfecting need to be part of the equipment instructions, supplied by the manufacturer of the equipment.

### **1.6.2 Contact materials**

General rules concerning contact materials are defined in Regulation (EC) 1935/2004 (EC 2004d). This legislation is applicable to materials which are intended to be brought into contact with food (such as surfaces of machines), which are in contact with food and are intended for that purpose (such as packaging materials of packed food) and for materials which can be reasonably expected to be brought into contact with food or to transfer their constituents to food under normal foreseeable conditions of use. These materials may not give any risk to either the safety of the food product, nor its organoleptic characteristics.

Food contact materials need to be clearly labelled that they are allowed to be in contact with food. This can be with the words 'for food contact' or by a symbol. Where necessary, instructions for use need to be defined. These materials also need to be accompanied by a declaration of compliance, in which it is stated that they comply with the rules applicable for them and, where applicable for the intended use and/or limitation in the use.

The materials and articles need to be ensured at all stages of the chain, to make sure the products can be traced back in case there are issues identified. As for food products, this traceability needs to be guaranteed one step back and one step forward.

For some types of materials there is already clearly defined legislation, e.g. for plastic materials, which are stated in Regulation (EC) 10/2011 (EU 2011a). For other types of materials, this is not (yet) the case. Where guidance is not available in the EU, the requirements of the USA Food and Drug Administration on food contact materials (FDA 2013) can be adopted.

Requirements concerning the production situation of the food contact materials are stated in Regulation (EC) 2023/2006 (EC 2006c). In this legislation, the GMPs for the production of these materials are defined. These requirements are less stringent as the requirements defined in Regulation (EC) 178/2002 (EC 2002) for the production of food stuffs.

## 1.7 Hygiene regulations in relation to private food safety standards

To ensure suppliers compliance with legal food safety requirements for which also the customers are responsible, such as the general food law and the H1/H2/H3 regulation. These requirements are also adopted in various private food safety standards, such as BRC, IFS, ISO 22000, FSSC 22000. In these standards, much attention is also given to contact materials and equipment design. These requirements are mostly taken in the prerequisite programmes, but on top of that, a risk analysis, based on the HACCP principles is demanded.

Requirements which are also taken in the food safety standards are management principles, as defined in ISO 9001:2008 (ISO 2008), to achieve continuous improvement and customer satisfaction. This is shown in a schematic way in Fig. 1.1.

## 1.8 Conclusion

The HACCP rules were originally meant for operators in the food industry, but are more and more used for the entire food chain, including suppliers of services, packaging and equipment. Most of the requirements towards equipment are defined in prerequisite programmes, but are more and more emphasized by the regulator.

## 1.9 Sources of further information and advice

- <http://eur-lex.europa.eu>
- [http://ec.europa.eu/food/food/foodlaw/principles/index\\_en.htm](http://ec.europa.eu/food/food/foodlaw/principles/index_en.htm)
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## 2

# Hazards, sources and vectors of contamination

**H. L. M. Lelieveld, formerly Unilever R&D, The Netherlands and  
J. T. Holah, Campden BRI, UK**

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**Abstract:** Contaminants in food can be biological, chemical or physical hazards. Hazards in the raw materials, packaging and the process are controlled by the HACCP plan with additional controls in the quality plan. Hazards in the processing environment are controlled by HACCP prerequisites. This chapter offers a new concept on how these hazards can be analysed, controlled and managed. The processing environment plan (PEP) considers the sources of contamination and their vectors. It then determines and implements the controls to reduce the risks and if these risks are critical to the safety of the product, recognises the controls as operational prerequisites (OPs), which are managed in a similar manner to critical control points (CCPs) in the HACCP plan.

**Key words:** hazard analysis critical control point (HACCP), prerequisites, hazard, source, vector, process environmental plan (PEP), operational prerequisite (OP).

## 2.1 Introduction

The three main types of food contaminants are physical, chemical and microbiological. Foods can become contaminated during growing and harvesting of raw materials, storage and transport to the factory and processing into finished products. Finished products may then be contaminated during subsequent storage and transport to retail display, as well as during storage and preparation by the consumer.

The passage of food material over a surface leaves residual food debris in unhygienic surface features that encourages the growth of any microorganisms harboured in these areas. From such a source, microorganisms can multiply to sufficient numbers that they affect the safety or quality of the food. The build-up of food debris, which may deteriorate when out of the main product flow, will also have an impact on product quality if it subsequently returns to the main product flow. Chemical contamination

may also result from these contact surfaces if they are not adequately rinsed after cleaning and disinfection regimes. Lubricants, often unavoidable in equipment with moving parts, may contribute to chemical contamination (Steenard *et al.*, 2009). Non-product contact surfaces, such as floors, walls, ceilings, overhead beams and equipment supports, are also important. As well as being reservoirs of microbial contamination, they can also be a source of physical and chemical contamination (e.g. from flaking plaster and the chemical residues within it). They need to be designed so that they are durable and can be effectively cleaned.

The main vectors of contamination are through contact with surfaces (food contact surfaces and packaging), the air (or other gases), with water (or other liquids) or with people (or animals and insects) (Holah, 1999).

Air can be a significant medium for the transfer of contamination to food products (Curiel and Lelieveld, 2013). Unless the air is treated, microorganisms will be present, and the air is also a contamination route for 'light' foreign bodies such as dust, straw-type debris and insects. Chemical taints can enter the production area through airborne transmission. Water is used in the food industry as an ingredient, as a production process aid (cooling, washing, fluming) and for cleaning. Its use as an ingredient and as a processing aid can give rise to potential microbial or chemical contamination problems, and so it is important to use water of a high microbiological and chemical quality (i.e. of potable quality). Water used in handwashing facilities also poses a potential problem. Unwanted water, such as from steam or water vapour, condensation, leaking pipes or drains, or rainwater, can also be a vector for contamination. Stagnant water is particularly hazardous, as microbes can multiply rapidly under favourable conditions. The water used in cleaning and sanitising regimes also needs to be of adequate quality. See Holah (1997) and Dawson (1998, 2000) for further information on the quality and use of water in the food industry.

People are a large reservoir of microorganisms, and gastrointestinal infections, for example, can be transferred to food (e.g. via aerosol droplets resulting from coughing near the process line) (Guzewich and Ross, 1999; Todd *et al.*, 2007). Pathogens on hands are also a major potential source of contamination (Smith, 2009). People can also be a vector for contamination of food with physical hazards such as hair or fingernail fragments, earrings, plasters and small personal belongings. Pests such as birds, insects and rodents are a major contamination problem, and are known to carry pathogens such as *Salmonella* spp. and *Clostridium botulinum*, and particular care needs to be taken to prevent their entry into food production areas. Buildings need to be designed to keep them out. Floors, ceilings and walls need to be designed so that they do not allow insects and other invertebrates the chance to live and breed (Holah and Lelieveld, 2011).

Finally, and unfortunately, people have deliberately contaminated foods for political or bioterrorism reasons (Federation of American Scientists, <http://www.fas.org/biosecurity/education/dualuse-agriculture/1>).

-agroterrorism-and-foodsafety/deliberate-contamination-foods.html), for revenge, e.g. disgruntled ex-employees, or for criminal extent, e.g. extortion or blackmail.

## 2.2 Physical contaminants

Food can be contaminated by physical objects commonly known as foreign bodies. There is a huge range of foreign bodies reported in foods, arising from many different sources. These can be of biological origin:

- leaves, stalks and other extraneous pieces of plant material associated with fruit and vegetables;
- soil and stones associated with harvested fruit and vegetables;
- bone or organ tissue associated with raw meat;
- insect and animal parts or residues in raw materials or resulting from infestation during processing;

or synthetic:

- glass, metal and plastic fragments associated with either raw materials or the processing environment.

Foreign bodies can be either present in raw materials or introduced during food processing operations. Their prevention depends in part on good agricultural practices on the farm, particularly in the way crops are harvested and cleaned prior to dispatch, or how well cattle are maintained as well as the quality of slaughtering operations. Good practices amongst raw material suppliers can substantially reduce the number and range of foreign bodies that a food processor has to deal with.

Food processors can ensure a minimum standard for raw materials through a supplier quality assurance scheme. The EU, for example, has minimum standards for horticultural product quality (Anon., 1996a, 1996b, 1996c). Many companies issue their own individual company specifications, which are normally more stringent than the EU standards. They also enable the company to be more specific in their individual requirements. The following categories covering foreign bodies are often included (Bedford, 2000):

- Foreign matter (FM) – material of non-plant origin. This includes stones, soil, wood, glass and insects, and any other material such as plastic, which may have become included in the load. This category also includes any toxic material of plant origin such as potato or nightshade berries in vegetable crops. There is usually a nil tolerance for all these items, with the possible exception of insects. It may be impossible to achieve complete absence of insects, as even after chemical treatment they may remain in the dead state often hidden within the leaves of such items as lettuce and calabrese.



- Extraneous vegetable matter (EVM) – parts of the crop plant other than that to be consumed, e.g. bits of stem in a consignment of Brussels sprouts or leaf in green beans. Small amounts may be allowed.
- Foreign EVM (FEVM) – parts of plants other than the crop species. Small amounts may be allowed. This category does not include any toxic material (see FM above).

There are two priorities in dealing with foreign bodies in a factory setting. The first is adequate procedures for identifying and removing any remaining foreign bodies contaminating raw materials coming into the factory. The second is to ensure that the processing environment itself does not become a source of foreign bodies. Such contamination may happen in a number of ways:

- Through personnel handling of food (hair, fingernails, plasters for cuts, or jewellery, for example).
- Through badly designed or maintained equipment (metal or plastic fragments, rust or loose nuts or screws, fragments of packaging material).
- Through poorly designed or maintained buildings (for example, peeling paint, glass or wood splinters).
- Through inadequate design and procedures for the control of pests, whether insects, animals or birds.

## 2.3 Chemical contaminants

The main groups of chemical contaminants that can be found in food share the following characteristics:

- They are not intentionally added to food.
- Contamination can happen at one or more stages in food production.
- Illness may result if consumers ingest enough of them.

The first of these points distinguishes chemical contaminants from other chemicals in food, e.g. vitamins and additives. The wide range of possible sources of chemical contamination has major resource implications, particularly in controlling chemicals that find a wide range of uses, for example pesticides. In order to ensure consumer and worker protection, very careful attention must be given at all stages in food production. There are various types and sources of chemical contaminants:

- pesticides and veterinary residues arising from agricultural production;
- naturally occurring toxicants;
- environmental contaminants;
- hazardous chemicals formed during processing;
- migration from packaging;
- contamination during processing;
- residues of cleaning and sanitation chemicals.



A wide range of practical steps can be taken to control pesticide and veterinary residues in food, including the following:

- Providing clear guidance and setting appropriate limits for use.
- Effective surveillance and enforcement regimes by government.
- Including these procedures and limits in supplier quality assurance schemes.
- Testing incoming supplies of raw materials.

It is important to recognise that the use of pesticides near crops and farm animals, and in factories concerned with food production, can also lead to residues in food (Shaw and Vannoort, 2001). This can be particularly difficult to detect if surveillance for residues looks mainly for those pesticides used directly on crops or farm animals. The remedy is to extend surveillance and to enforce national standards in the use of these chemicals. There are three basic types of naturally occurring toxicants (Watson, 1998):

- Toxins produced by microbial contamination of food and raw materials used in food production.
- Toxins produced by crops (in some cases at least to protect the plants from insects).
- Toxins ingested by food-producing animals.

The first category includes toxins produced by fungi (mycotoxins) and bacteria. The second group includes a wide range of food-producing plants. The third is a small group of marine toxins, mostly produced by dinoflagellate algae that find their way up the food chain and to the consumer. Considerable progress can be made in protecting consumers from many of the natural toxins in food by applying good agricultural practices and through the careful handling of food. As an example, crop rotation can reduce mycotoxin contamination, as can keeping stored grain and seeds dry (Moss, 2002). Bacterial toxins are much less likely to be found in food if hazard analysis critical control point (HACCP) systems are applied in food production. Plant breeding can lead to higher as well as lower levels of toxins. Polychlorinated biphenyls (PCBs) and dioxins have been perhaps the most widely studied environmental contaminants in food. PCBs were used in a wide variety of industrial applications and are very persistent contaminants, both in the general environment and in human fat (Steering Group on Chemical Aspects of Food Surveillance, 1983). In theory the routes of entry into food are:

- uptake from the environment by food-producing animals, particularly those with high fat content (as PCBs are lipophilic);
- direct contamination of food or animal feed;
- migration from packaging into food, just as other chemicals in packaging can migrate into food.

Known sources of dioxins now also include vehicle exhausts, domestic coal fires, manufacture and use of organic chemicals, and metallurgical processors. Two main types of contamination of food appear to be involved: atmospheric deposition and spreading of sludge, in both cases on farmland (Harrison, 2001a). Other environmental contaminants in food include metals and a yet to be defined number of the organic chemicals used in industry (Harrison, 2001b). Metal contamination of food can occur in a wide variety of ways, including environmental and other sources such as canning. Control depends on effective surveillance of food for environmental chemical contaminants. Toxicological standards can be used to define whether or not surveillance results show there is a hazard to consumer health. Both of these types of approaches are now standard in the best surveillance programmes.

It has been very difficult to predict which chemicals might be formed during food processing and might pose a hazard to consumers. There are already a few established examples:

- There is evidence that carcinogenic *N*-nitrosamines can be formed during the production of alcoholic beverages, fermented foods and cured meats (Steering Group on Chemical Aspects of Food Surveillance, 1992).
- Carcinogenic polycyclic aromatic hydrocarbons can contaminate smoked food (Bartle, 1991), although the main dietary sources of these compounds in the UK appear to be early in food production.
- 3-Monochloropropane-1,2-dio (3-MCPD) and ethyl carbamate have both also proven to be unwanted contaminants that are formed during food processing (JFSSG, 1999a; Food Standards Agency, 2000).
- Acrylamides are formed when food is processed or prepared at high temperatures, if the product contains both fats and carbohydrates and/or proteins. Acrylamides are potentially carcinogenic (FAO/WHO, 2002).

Early work on phthalate esters and several monomers such as styrene used to make plastics demonstrated that chemical migration can occur from packaging into food. There has been a huge amount of practical work on this over the last 30 years (Various authors, 1997), much of it on plastics. Thus there are now in place detailed controls on this aspect of plastics in the European Union (EU) and the USA (FCM Unit, 2000). Less is known about chemical migration from other packaging materials. Paper and board have been subjected to surveillance which so far has shown that some chemicals can migrate from it into food (e.g. diisopropylnaphthalenes; JFSSG, 1999b). Contamination during processing can come from a range of sources, including the following:

- lubricants;
- cleaning detergents and sanitisers;

- floor, wall and ceiling coatings and resins (including paint);
- pesticides used in the factory.

## 2.4 Microbiological contamination

Pathogenic microorganisms are the major safety concern for the food industry. As they are generally undetectable by the unaided human senses (i.e. they do not usually cause colour changes or produce off-flavours or taints in the food) and they are capable of rapid growth under favourable storage conditions, much time and effort have been spent in controlling and/or eliminating them. Even if microorganisms in a food are destroyed by a subsequent cooking process, they may have previously produced toxins, so the prevention of contamination through good hygienic regimes remains vital. The major food pathogens include the bacteria *Bacillus cereus*, *Campylobacter*, *Cl. botulinum*, *Clostridium perfringens*, *Cronobacter*, *Escherichia coli*, *Listeria monocytogenes*, *Salmonella*, *Staphylococcus aureus*, *Vibrio* and *Yersinia enterocolitica*, the hepatitis and noro viruses and the protozoans *Cryptosporidium* and *Giardia*, a summary description of which is given in Jones (2012).

Pathogenic microorganisms can enter food processing areas from four main routes: the external environment, raw materials, people (infected food operatives, contractors, visitors, etc.) and laboratories undertaking pathogen testing. Microorganisms from the external environment are controlled by the design of the factory building and its segregation. Microorganisms in raw materials are controlled by the HACCP plan, whilst infected food handlers are managed by best practice personnel hygiene prerequisites. The requirement for pathogenic microorganisms in accredited food laboratories is essential as they are used as media positive controls. They are controlled by the complete isolation of the laboratory from the factory, including air systems, drainage systems, waste removal, and the movement of laboratory staff and utensils (sample holders, sampling devices, sampling media, etc.).

As well as pathogenic microorganisms, spoilage organisms either can be naturally present or can gain access to food. Whilst not a food safety concern, increased levels of spoilage organisms will usually mean a reduction in the length of time that the food remains fit to eat. This can affect product quality and so also influence the consumer's perception of the product. The major food spoilage microorganisms include the bacteria *Acinetobacter*, *Alcaligenes*, *Alicyclobacillus*, *Brevibacterium*, *Brocothrix*, *Clostridium estertheticum*, *Corynebacterium*, *Flavobacterium*, lactic acid bacteria, *Moraxella*, *Pseudomonas* and *Xanthomonas* and the fungi (yeasts and moulds) particularly *Dekkera*, *Penicillium*, *Saccharomyces* and *Zygosaccharomyces*, a summary description of which is given in Jones (2012).

Growth of microorganisms will depend on a number of factors, such as temperature, humidity/water activity ( $a_w$ ), pH, availability of nutrients, presence or absence of oxygen, and inhibitory compounds such as preservatives. Different organisms require different conditions for optimal growth (e.g. some grow only in the absence of oxygen, others prefer either warm or cool conditions). Bacterial growth is by simple division of one cell into two (binary fission), and their number will increase exponentially under favourable conditions. The effects that factors such as temperature, oxygen, pH and  $a_w$  have on microbial activity may be dependent on each other. Microorganisms generally become more sensitive to oxygen availability, pH and  $a_w$  at temperatures near growth minima or maxima. Often, bacteria grow at higher pH, higher  $a_w$  and lower temperature under anaerobic conditions than when aerobic conditions prevail. Microorganisms that grow at lower temperatures are usually aerobic and generally have a high  $a_w$  requirement. Lowering  $a_w$  by adding salt or excluding oxygen from foods (such as meat) that have been held at a refrigerated temperature dramatically reduces the rate of microbial spoilage. Normally, some microbial growth occurs when any one of the factors that controls the growth rate is at a limiting level. If more than one factor becomes limiting, microbial growth is drastically curtailed or completely stopped. Effective control of pathogenic and spoilage bacteria thus depends on a thorough understanding of the growth conditions favouring particular pathogens. This understanding can be used to minimise contamination of incoming raw materials, to inactivate bacteria during processing and prevent decontaminated food from becoming recontaminated.

## 2.5 Hazard sources

The source of hazards may be the constituent raw materials of the product or the processing environment up until the product is packaged. Once packaged, foodstuffs may still (rarely) be contaminated through failings of the packaging, events that puncture the packaging or deliberate contamination. The retailer should inspect foodstuffs prior to retail display and not offer goods for sale that are obviously damaged and there is also some onus on the final consumer to reject foodstuffs and alert the retailer if packaging is damaged.

For the constituent raw materials, many food manufacturers have a *Management of purchased materials* policy as part of their quality system, which takes a proactive and reactive view to managing hazards (Table 2.1). The proactive requirements, which aim to minimise hazard contamination, are for a *Specifications for raw materials and packaging* policy which clearly defines the specifications and the methods of growing/manufacturing the raw material/packaging and, where appropriate, a *Provenance, assured status and claims of identity preserved materials* policy, which is a further

guarantee of the quality of the raw materials growing and processing. Further to this, the food manufacturer can audit their suppliers, with a specific focus on hazard control, or can rely on a third party to undertake this for them to a recognised audit standard, as part of a *Supplier approval and control* policy. Reactive controls occur at the food manufactures site and include all inspection and testing of the raw materials and packaging on intake to the factory, as required by the *Product inspection and laboratory testing* policy. Procedures to actively remove hazards from the raw materials or packaging are controlled by the food product's HACCP plan.

Within the processing environment, hazards may be obvious, may need to be captured or may be required to be identified and/or quantified by growth (microorganisms) or chemical reactions (allergens). Obvious hazards include glass, metals and other foreign bodies arising from equipment and lubricants. They are controlled via frequent inspection and audit and as part of the *Glass breakage* and *Maintenance* policies (Table 2.1). Other obvious hazards include the use of cleaning detergents and disinfectants and other chemicals such as pesticides that are handled by factory operatives. If these are handled correctly following good hygiene practices (GHPs) such as the *Cleaning and disinfection* and *Pest control* policies (Table 2.1), these hazards should be adequately controlled. Less

**Table 2.1** A list of typical HACCP prerequisites required for the design and control of the food manufacturing infrastructure and generic quality system prerequisites that have an impact on hazard control. Further information on the hygiene prerequisites can be found in the indicated chapters of this book

Hygiene prerequisites		
	Chapter	Quality prerequisites
<i>Hygienic infrastructure</i>		
Factory design	3	Management of purchased materials
Process lines and equipment	4/5	Supplier approval and control
Services	8	Specifications for raw materials and finished product
Ventilation and air flows	7	Packaging specifications
Medical screening	12	Provenance, assured status and claims of identity preserved materials
<i>Hygienic practices</i>		
Maintenance	11	Raw material controls
Cleaning and disinfection	9, 10	Product inspection and laboratory testing
Personal hygiene	12	Traceability
Pest control	14, 15	Glass breakage policy
Waste disposal	3	Customer complaints
Environmental sampling	16	Control of non-conforming products/quarantine

obvious chemical hazards include solvents released from, for example, floor, wall and ceiling coatings and resins (including paint) though attention to appropriate selection of such finishes and/or correct installation/refurbishment procedures should limit their risks.

Pests may be observed directly or via signs of their presence (e.g. droppings, gnawing, body smears or insect parts), but are more likely identified via capture techniques (rodent bait box traps, UV fly traps, etc.). These are identified in the *Pest control* policy (Table 2.1). Methods for the detection of microorganisms and allergens are described in the *Environmental sampling* policy (Table 2.1). Where allergens and microorganisms differ, however, is that allergens are derived from known food ingredients, their presence on surfaces is predictable, and their detection on surfaces is for the purpose of verification that techniques devised for the removal of all allergen residues (cleaning) are under control. Microorganisms, however, can be sourced from both the product ingredients and the environment and thus the presence of microorganism cannot be predicted.

Once within the processing environment, pathogens can be sporadic visitors, being present until they lose viability or are removed via cleaning and disinfection procedures or more persistent, surviving in harbourage sites or growth niches to form sources of contamination. Harbourage sites are physical areas in which pathogens can lodge and be protected from external forces such as cleaning and disinfection actions, e.g. poor hygienic design features of processing equipment, damaged surfaces (e.g. conveyor belts) or damaged areas of the plant's building structure. Microorganisms are specifically adapted to adhere to surfaces where they can resist environmental stresses and persist in food factories for long periods of time, for example 10 years (CDC, 2008). Growth niches are also harbourage sites, but which also provide an environment for growth, e.g. nutrients, temperature, oxygen, water or humidity and lack of competition from other microbial flora.

The growth of environmental microorganisms can have a significant impact on food products. There are usually places in process lines, even if correctly designed, where some product resides longer than desirable. Even if dead areas have been designed out, some product will attach to equipment surfaces, even at high liquid velocities. Microorganisms may reside on such surfaces long enough to multiply. With the increase in the number of microorganisms, the numbers washed away with the product increase as well, leading to eventual contamination. The problem is exacerbated if a process includes dead spaces where product can stagnate. As an example, if a cell of *E. coli* is trapped in a dead space filled with 5 ml of a lightly viscous low-acid food product at a temperature of approximately 25°C, it may take less than 24 hours for the number of *E. coli* cells to increase to a concentration of  $0.2 \times 10^9$  per ml, assuming they double every 40 minutes (Lelieveld, 2000). If every hour just 1 ml is washed out from the dead space by the passing product, by the end of the first day of production the product

is infected with 200 million *E. coli* cells each hour. If the production capacity of the line is 5 million ml per hour, the average *E. coli* contamination will be  $200/5 = 40$  per ml. Many traditional process lines have much larger (often very contaminated) dead spaces and growth rates can be higher if conditions such as temperature are favourable. Microorganisms may also penetrate through very small leaks. There is considerable evidence that microorganisms may pass microscopic openings very rapidly and that pressure differences may retard but not prevent passage, even if the pressure difference is as high as 0.5 bar. *Serratia marcescens* may move at a speed of 160 mm per hour (Schneider and Dietsch, 1974). Motile bacteria may therefore propel themselves against the flow of liquid through a leak. Microorganisms, motile or not, may also grow through a passage by forming a biofilm on the surface. Studies of the migration of microorganisms through microscopic passages show the passage of microorganisms through holes of a few micrometres in diameter in a metal plate of 0.1 mm thickness (Brénot *et al.*, 1995).

Following surface attachment, microorganisms can also initiate surface growth. As they grow and multiply, the newly formed cells attach to each other as well as to the surface, forming a growing colony of microorganisms. When this mass of cells becomes sufficiently large that it entraps debris, nutrients and other microorganisms, a microbial biofilm is established (IFT, 1994). Biofilms form in two stages. First, an electrostatic attraction occurs between the surface and the microbe. The process is reversible at this state. The next phase occurs when the microorganism exudes an extracellular polysaccharide, which firmly attaches the cell to the surface. The cells continue to grow, forming micro-colonies and, ultimately, the biofilm. These films are very difficult to remove during the cleaning operation. Microorganisms that appear to be more of a problem to remove because of biofilm protection include *Pseudomonas* spp. and *L. monocytogenes* (Notermans *et al.*, 1991). Biofilm development may take place on any type of surface and is difficult to prevent if the conditions sustain the multiplication of microorganisms. Many microorganisms, including many pathogens (*L. monocytogenes*, *Salmonella typhimurium*, *Y. enterocolitica*, *Klebsiella pneumoniae*, *Legionella pneumophila*), form biofilms, even under hostile conditions such as in the presence of disinfectants. Adverse conditions may even stimulate microorganisms to grow in biofilms (van der Wende *et al.*, 1989; van der Wende and Characklis, 1990). Thermophilic bacteria (such as *Streptococcus thermophilus*) can form biofilms in the cooling section of milk pasteurisers, sometimes within five hours, resulting in massive infection of the pasteurised product (up to  $10^6$  cells per ml) (Driessen and Bouman, 1979; Langeveld *et al.*, 1995).

On metal (including stainless steel) surfaces, biofilms may also enhance corrosion, which may result in microscopic holes. Such pinholes allow the passage of microorganisms and thus may cause infection of the product. Like other causes of fouling, biofilms will also affect heat transfer in heat exchangers. On temperature probes, biofilms may seriously affect heat



transfer and thereby the accuracy of the measurement. Reducing the effectiveness of heat treatment may itself help to stimulate further bacterial growth. On conveyor belts and on the surfaces of blanching equipment, for example, biofilms may infect cooked or washed products, which are assumed to have been made pathogen-free by the temperature treatment received. Biofilms may be much harder to remove than ordinary soil. If the cleaning procedure is not capable of completely removing biofilms that may have developed, decontamination of the surface by either heat or chemicals may fail as biofilms dramatically increase the resistance of the embedded microorganisms (IFT, 1994). It is thus imperative that product contact surfaces are well cleaned before disinfection.

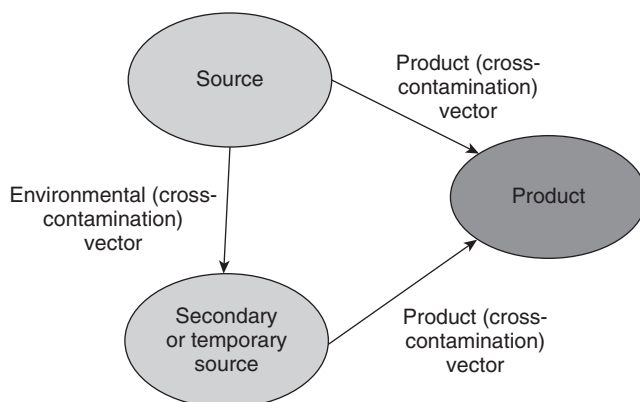
Krysinski *et al.* (1992) studied the effects of a variety of cleaning and sanitising compounds on *L. monocytogenes* allowed to attach to stainless steel and plastic material used in conveyor belts for 24 hours. They found that sanitisers alone had little effect on the attached microorganisms even when the sanitiser exposure time was increased to 10 minutes. Unattached cells, on the other hand, showed a 5-log reduction in numbers in 30 seconds. In general, acidic quaternary ammonia, chlorine dioxide and peracetic acid were the most effective sanitisers on attached cells. Least effective were chlorine, iodophors and neutral quaternary ammonium compounds. When the attached microorganisms were treated with cleaning compounds prior to treatment with sanitisers, the bacteria were inactivated.

## 2.6 Hazard vectors and controls

### 2.6.1 Hazard vectors

Microorganisms from harbourage sites and growth niches and, perhaps less frequently, from the general environment as sporadic contaminants, can be transported to food products via three prime vectors. These are physical contact with a solid, animate or inanimate surface, physical contact with a liquid or settlement and/or impingement from the air (or other gases). The difference between solid contact and liquid contact is that the liquid may be absorbed into the food product, which may increase the transfer of microorganisms to the food (towards 100%). For contact between solid surfaces, microorganisms will partition to and from the two surfaces, dependent on the physical properties of the microorganisms and surfaces. Smith and Holah (2007) demonstrated that the transfer of microorganisms from one food contact surface to another (e.g. hands, gloves, stainless steel, chopping boards) varied between 20 and 90% and can be approximated to 50% for practical purposes. For stationary air, transfer of microorganisms from the air is via sedimentation, which has defined rates for particles of given size (Stokes Law, cited in Lamb, 1994), and the number of microorganisms transferred is dependent on the microbiological loading of the air and the particle size on which they are carried and the exposure





**Fig. 2.1** Transfer of pathogens from likely sources directly to food products via product vectors or indirectly to secondary or temporary sources.

time. When the product is transported via air, or when air is forced into the product for cooling or drying purposes, microorganisms can enter the product via impingement in addition to sedimentation, and the number of microorganisms transferred may be related to the microbial loading and volume of air that the product is exposed to.

Microorganisms may transfer from sources directly to the food product, on product vectors, or indirectly to other parts of the processing environment via environmental vectors (Fig. 2.1). If observational and microbiological data identify likely pathogen sources, all potential environmental contamination routes from this identified source should be determined to identify the potential for secondary or temporary sources.

Food product vectors include: (surfaces of) food production equipment, utensils, transport containers, hands, inspection activities and sampling activities; (liquids, such as) fluming water, cooling water, leaks directly over product, cleaning residues remaining on surfaces and ballistic cleaning droplets from environmental cleaning activities; (air) air knives, product transport via air, product cooling via air and direct product contact with compressed air.

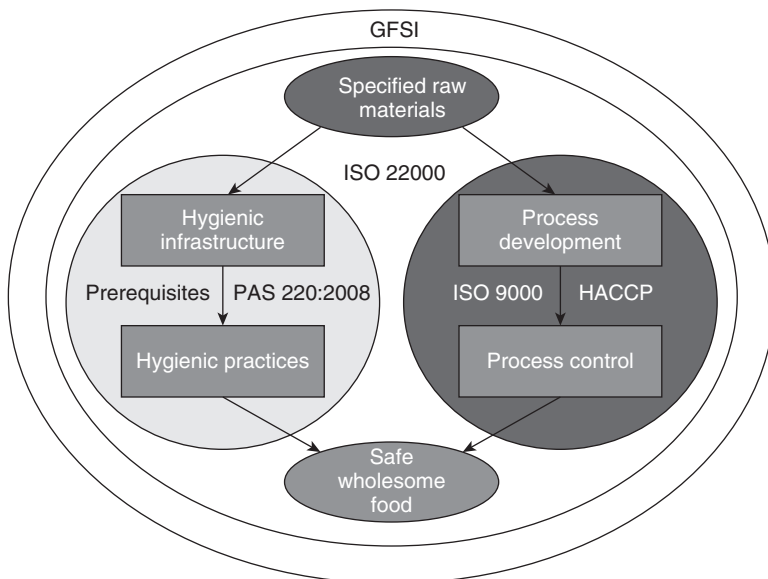
Food product contamination usually occurs as a contamination event, in which a number of vectors may be involved. For example, entering a food product stream to help clear obstructing product, may have vectors of the operator's hand (or glove), the operator's sleeve, the tool to be used for cleaning away product debris and the air. In some instances the contamination event could have only a single vector e.g. contaminated water droplets from a compressed air line.

Environmental vectors include: (surfaces) traffic patterns for product containers, packaging, waste products, production operatives, quality control functions, maintenance and management activities; (liquids) leaks from

roofs and pipework systems, cleaning aerosols (e.g. from high-pressure hoses) and condensate; (air) room air intakes, fans on motors, evaporative condensers, air extracts, e.g. extract hoods over fryers or traywash areas, air movements through drains, compressed air release from pneumatic systems.

### 2.6.2 Hazard controls

All food factories have traditionally required a supply of raw materials and packaging, a hygienic manufacturing infrastructure and hygienic practices to maintain it, and an appropriate manufacturing process and process controls to ensure that all packs in all batches receive the same process (Fig. 2.2). Within food factories, hazards are primarily controlled by three programmes: HACCP prerequisites, the HACCP plan and the quality system. Hazards within the raw materials and from processing are primarily controlled by the HACCP plan, typically based on the requirements of CODEX (Anon., 1993) and practically described by Mortimore and Wallace (1998) and Gaze (2009). In addition, generic hazard controls are also detailed in the quality system as typified by ISO 9001 (Anon., 2008a). Hazards from within the manufacturing infrastructure are controlled by HACCP prerequisites, described in PAS 220:2008 (Anon., 2008b). The relationship between these three controls is shown schematically in Fig. 2.2.



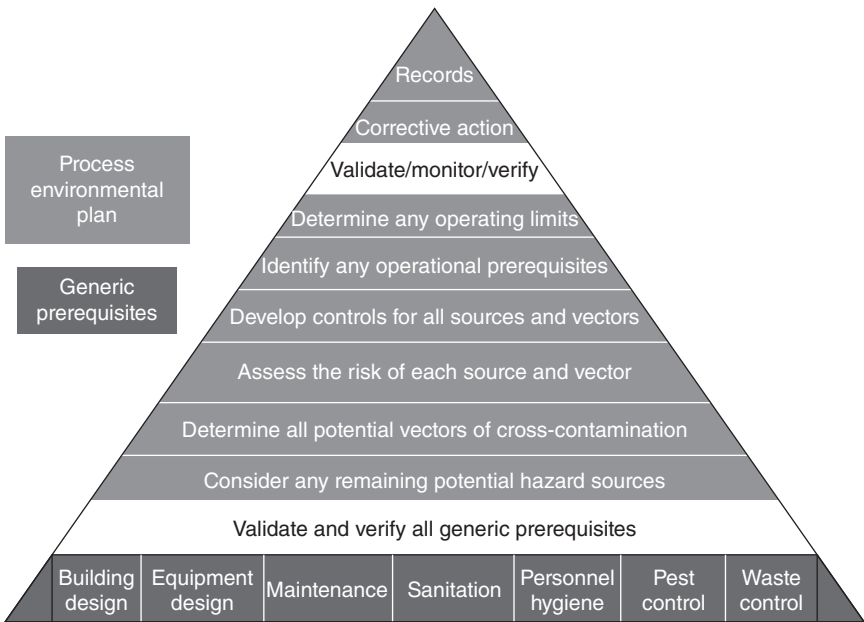
**Fig. 2.2** The management of food safety via HACCP prerequisites, the HACCP plan and quality management systems (GFSI = Global Food Safety Initiative).

More latterly, an international standard has sought to bring together into one standard the requirements of these three food safety plans and this has been published as ISO 22000 (Anon., 2005). Food retailers have also been active to ensure the third party auditing of such food safety plans, under the management of the Global Food Safety Initiative (GFSI) ([www.mygfsi.org](http://www.mygfsi.org)). This organisation has harmonised the requirements of the major food standards organisations that produce auditable food standards such as the British Retail Consortium (BRC, 2011), International Food Standard (Anon., 2012) and SQF (Anon., 2008c). For example, the BRC global standard for food safety requires food manufacturers to develop and comply with the following four key elements; senior management commitment, a quality management system, prerequisite programmes and a HACCP plan. Auditing standards approved by GFSI are clearly aligned to meet the requirements of ISO 22000 and this is represented by the external circle surrounding the ISO22000 circle in Fig. 2.2.

There is further information on HACCP systems in Chapter 1 of this book. Prerequisites related to the design and control of the manufacturing infrastructure, and in which chapters of this book they are addressed, are indicated in Table 2.1. Table 2.1 also lists some of the generic quality prerequisites that are detailed in quality systems (e.g. ISO 9001, Anon., 2008a).

Here we focus on the management of HACCP prerequisites. The role of prerequisites, particularly related to the role of the processing environment and how it can harbour hazards, which can be transferred on vectors to the product, has become especially important for microbial pathogen hazards in ready-to-eat (RTE) foods. In both North America and Europe, recent major incidents with *Listeria* in chilled products (Anon., 2008d; Jackson *et al.*, 2011) and *Salmonella* in dry RTE products (CDC, 2008, 2009) has focused attention on the processing environment. In the majority of these cases, contamination following the pathogen reduction stage (e.g. cooking or decontamination via chlorinated produce washing), often the last HACCP critical control point (CCP), is thought to be the route in which the product becomes contaminated. Post-process contamination is prevented and managed predominately by prerequisite programmes, and it can be argued that for certain products, such as RTE food products, to ensure the safety of these foodstuffs, the management of such prerequisites is as important as the management of CCPs where pathogens are killed, reduced to safe levels or prevented from growth.

To more effectively manage HACCP prerequisites, a prerequisite management plan (PMP) has been advocated by Holah *et al.* (2011, 2012). The PMP comprises two elements: generic hygienic food infrastructure and practices prerequisites and specific processing environment prerequisites. To manage the hygienic manufacturing infrastructure and practices a number of generic prerequisites are required which may be independent of the factory or the food manufacturing process it contains. Examples of these



**Fig. 2.3** Prerequisite management plan pyramid describing generic infrastructure prerequisites and prerequisites determined from a process environmental plan.

are shown in Fig. 2.3 as the base of a PMP pyramid and, indeed, all GFSI-based audits will require such generic prerequisites to be in place. Generic prerequisites should be undertaken to best practice standards and should be appropriately validated, monitored and verified.

After the implementation of generic prerequisites, food manufacturers then have to consider the management of any residual hazards that may contaminate food products during processing. Such hazards, and the transfer vectors via which they can contaminate the product, will be unique to each food manufacturer and each food manufacturing site. The assessment of hazards in the food processing environment, their risk and how they can be controlled by prerequisites to prevent contamination to the food product, can be described as the processing environment plan (PEP), which is schematically described in Fig. 2.3.

## 2.7 Recommended procedure for developing a processing environment plan (PEP)

The undertaking of the PEP follows the 14 principles or steps of the HACCP plan as defined by Gaze (2009) and has been described in detail in Holah (2013). A brief description of the 14 steps is detailed below.

### **2.7.1 Step 1: *obtain management commitment***

Senior management must be committed to providing the necessary resource for the study to be planned, undertaken, implemented and periodically reviewed. In many cases this may be implicit as the PEP and PMP could be seen as part of the HACCP plan which, for some countries, may be a legal requirement. Senior management should also appoint a manager and/or team leader to take responsibility for the plan's development and implementation.

### **2.7.2 Step 2: *define the scope or the terms of reference***

The processing area(s) for the study should first be determined. Secondly, the (biological, chemical or physical) hazards to be assessed should be considered, including their effect on product safety and/or quality. If the study is to focus on microbiological pathogens, the specific pathogen must be noted. This is because different pathogens may require different environmental niches to survive, grow or become established; for example in chilled environments, *Listeria* spp. may dominate in low temperatures and moisture (e.g. evaporative condenser trays), whereas *E. coli* require higher temperatures (e.g. surrounding motor drive shafts where friction creates higher local temperatures).

Lastly, the types of potential sources and routes (vectors) of environmental contamination transfer may need defining, particularly if these have already been considered at the generic prerequisite stage. For example and for most countries' climates, if the compressed air supply is dried to a dew point of  $-40^{\circ}\text{C}$ , it may not be necessary to consider the use of compressed air in a processing area as a source or vector of microbiological contamination.

### **2.7.3 Step 3: *select the environmental plan assessment team***

As the study will assess hazard sources and vectors within a given process area, many activities and events may occur in this area at different times of the day, week, year, etc., and the selection of team members should reflect all of these activities. Engineers will be required who understand the building's construction, food production equipment, service provisions and all maintenance activities. Production staff, sanitation managers, HACCP, technical and quality staff, and hazard specialists such as microbiologists, chemists and pest controllers (depending on the hazards in scope) will all be required. Particularly for small companies, consultants can be used for their technical knowledge, but they should not write the plan. The PEP should be owned, written, implemented and managed by the food manufacturer.

#### **2.7.4 Step 4: *describe the environment***

All physical and operational parameters of the processing environment under study should be measured and recorded with due regard to activities in adjacent processing areas, beside, below or above the area of study. Physical properties will include the size and layout of the processing area; any zones of segregation; entrance barriers into the area; services flowing through or above the area; air flows, temperatures and humidity; personnel flows; transport flows for product and packaging, and solid and liquid waste streams. Operational activities will include products processed, production lengths and seasonality; housekeeping, end-of-production and periodic cleaning and disinfection practices; maintenance activities and shut down periods.

With respect to the hazards of concern, any historical data from previous routine sampling or observational studies (e.g. routine environmental microbiological sampling, pest control records, glass and hard plastic records) should be recovered and reviewed.

#### **2.7.5 Step 5: *identify intended product use***

The intended use of the product should be established with respect to the fate of the hazard(s) in scope. Firstly, will there be any further treatment of the product or controls of the process line that might affect the removal, reduction or growth of any hazards entering the product directly or from the food production equipment? Secondly, as for a classic HACCP study and particularly for RTE foods, if there is no removal or reduction of the hazard, how will these hazards affect the target consumer group?

#### **2.7.6 Step 6: *construct flow diagram***

All information collected during Step 4 should be recorded in the form of physical maps or diagrams of the processing area. A base map of the processing area with the layout of food processing equipment and services should be constructed. Overlaying this map can be specific diagrams of, for example, alternative production equipment set-ups, air flows, personnel flows, transport flows and waste flows. The position of any subsequently identified hazard sources and contamination vectors can also be recorded.

#### **2.7.7 Step 7: *on-site confirmation of flow diagram***

The PEP team should audit the processing area at all processing, sanitation, maintenance and down times to ensure that the flow diagrams produced are accurate and representative.

### **2.7.8 Step 8: list all potential hazards, conduct a hazard analysis and consider any measures to control the identified hazards**

Within this step the PEP team conducts a thorough investigation of the processing environment to identify any hazard sources and any mechanisms or vectors via which these hazards could enter the food product directly or via food processing equipment. Step 8 according to Gaze (2009) equates to Step 1 of the 7 HACCP principles as defined by the Codex Alimentarius Commission (Anon., 1993) and, subsequently, steps 9–14 relate to Codex steps 2–7.

The investigation of sources and vectors in the following text is illustrated for microbial pathogens as the hazard, but is equally applicable to the analysis and control of other hazards. The determination of potential pathogen sources and contamination vectors in a processing plant is a combination of physical examinations, microbiological sampling and the review of microbiological records. Sources can be determined by dismantling process equipment to identify potential harbourage sites and niches, together with physical inspection of the building structures and finishes. The potential presence of pathogens in such harbourage sites and niches can be determined by microbiological sampling and over prolonged periods (e.g. via environmental microbiological sampling records), an indication can be gained as to the likelihood of pathogens being present in these sites. The observation of all potential sources should be recorded as a record of the environmental survey, for example in a tabulated form as shown in Table 2.2. In this example, taken from one of the author's experience, meat residues were found inside a switch, which had to be pressed to operate a meat slicing machine every time a log of meat was placed on the slicer. Any contamination in the switch could be transferred from the operative's finger to the meat log or to any other environmental surface that the operative touched.

Contamination vectors can be identified by inspection of all of the activities associated with the production line and processing environment reflecting all operating conditions including process type, product type, time of day or batch process, cleaning and disinfection, maintenance procedures, quality control (QC) procedures, production down times and any seasonal events. Observations of contamination vectors should be made independently of known or likely pathogen sources, because contamination could arise from temporary sites, and is best observed from the process itself – i.e. the identification of potential transfer vectors to the process line, observed from the process line. Observational data for vectors should also be recorded as indicated in Table 2.3. In this example, taken from one of the author's experience, the nozzles that inject milk into the top of a milk spray dryer have to be removed every day so that they can be cleaned of deposits that affect the operational efficiency of the dryer. During the removal and replacement operation, contamination from hazards could enter the dryer.

**Table 2.2** Potential sources of *Listeria* contamination detected around a meat slicer in a high risk food production area that is no longer in existence (Holah 2013)

Process step or environment	Observation	Source hazard analysis without controls				Source hazard analysis with controls			
		Likely hazard	Microbial source presence LMH	Potential to spread via environmental vectors LMH	Risk score	Current or intended control	Microbial source presence LMH	Potential to spread via environmental vectors LMH	Risk score
Meat slicer	Meat residues were seen on the inside of a switch that operated the meat slicer. When the switch was pressed in to start the machine slicing, the movement of the switch into its housing extruded meat residues onto the food operative's finger. If <i>Listeria</i> was present in the switch (which has occurred in previous installations) it could be transferred to the meat by contact with the operative's finger. Routine microbiological sampling of the switch for <i>Listeria</i> was always negative	<i>Listeria</i>	Medium 2	Low 1	2	Switches routinely cleaned as part of the end-of-production sanitation programme	Low 1	Low 1	1



**Table 2.3** Potential sources of *Salmonella* in a milk spray drying operation that has been subsequently refurbished (Holah 2013)

Process step or environment	Observation	Likely hazard	Product vector analysis without controls						Product vector analysis with controls					
			Contamination event vector	Potential presence on vector			Frequency of vector	Severity of hazard	Risk score	Subsequent control step	Current or intended controls	Potential presence on vector		
				LMH	LMH	LMH						LMH	LMH	LMH
Milk spray drying	Approximately once per shift, milk injectors are removed from the dryer, cleaned, disinfected and reinserted.	<i>Salmonella</i>	Dryer nozzles touch hands (gloves), tools and the dryer prior to entry	H	H	H	3	3	27	None	Gloves are worn and nozzles, tools and dryer contact surfaces are decontaminated with alcohol prior to dryer entry	L	H	H
				3		3						1	3	3
														9

When observing and identifying potential contamination sources and vectors with the PEP team, any current direct controls of observed sources and vectors should be recorded as illustrated in Tables 2.2 and 2.3. For vectors, subsequent controls within the food process may have an effect on the hazard that could be transferred by the contamination event, and these should also be recorded.

When undertaking a process environment study, many potential sources and contamination vectors could be observed, though the degree of control necessary for each source and vector will depend on their potential risk to food product contamination. Hazard analysis is fundamental to the HACCP process and can be used within the PEP plan. A risk analysis for a contamination source can be described as the risk of a pathogen being present at the potential source and the ability of the pathogen to be transferred from this source via an environmental and/or product vector. A risk analysis for a contamination transfer vector is a little more complex as it involves three factors: the potential for a pathogen being present on the product vector, the frequency of the vector and the severity of the impact of the hazard to the consumer of the product.

If a risk ranking of 1, 2 and 3 was used as a substitute for low, medium and high risk respectively, a multiplication range can then be used to determine a risk score, which can help describe the significance of the contamination source or vector. For a source, the risk score would be in the range of 1–9 whilst for a vector the risk score would be in the range of 1–27.

Risk ranking of sources and vectors should be recorded as illustrated in Tables 2.2 and 2.3, both before and after controls are applied. Undertaking a risk analysis before and after the application of any controls can help identify whether controls are necessary and/or whether current or intended controls are sufficient to reduce the risk of the source or contamination event. As a minimum, this allows consideration of the adoption of controls for the uncontrolled sources and vectors that the environmental study has identified, which may have an immediate impact on improved food safety.

Subsequent controls should also be considered when assessing the risk of a contamination event. In the dryer intervention example in Table 2.3, the removal, cleaning and insertion of the milk spray nozzles occurred every day, whilst cleaning in place (CIP) was undertaken every three weeks. Any microorganisms entering the dryer during these potential contamination events would not be subjected to a process control step.

### **2.7.9 Step 9: *determine operational prerequisites***

Control of food product contamination by hazards is a combination of reducing the number of possible hazard harbourage sites and niches, controlling those that microbiological sampling has previously identified that may be a known risk, removing all unnecessary contamination vectors

and controlling those that remain or are intrinsic to the food production process.

However, the control of some sources or vectors (prerequisites) may be more critical to the safety of the food product than others. The concept of a ranking system for prerequisites has been addressed by ISO 22000 (Anon., 2005), which differentiates operational prerequisites from prerequisites and defines them as being *identified by the hazard analysis as essential in order to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or processing environment*. ISO 22000 thus suggests that a hazard analysis may identify that there may be some sources or routes of contamination that are so important to the safety of the food product that their control is essential and are thus elevated as a higher classification of prerequisite, i.e. operational prerequisites (OPs).

The hazard analysis as described in Tables 2.2 and 2.3 for sources and contamination event vectors respectively can further be developed by considering the risk scores for the sources and vectors without controls. For the maximum risk score associated with the removal, cleaning and re-installation of the spray nozzles (Table 2.3), this score indicates that if these contamination events were uncontrolled, or more practically, if the required controls failed, there would be a significant risk of pathogens being present in the product. The control of these vectors is thus critical to the safety of the product and, based on this risk assessment approach, such controls could be described as OPs. OPs can be described in a tabulated form, as suggested in Table 2.4.

### **2.7.10 Step 10: establish control or operating limits**

Wherever possible, control or operating limits should be identified for each OP. These may be defined in legislation, codes of practice and other guidance documents, though the majority are likely to be determined from collection of experimental data during trials, e.g. cleaning validation data, or from the advice of experts. In some cases there may be lower and upper control limits, together with a target limit.

The specific control limits for each OP must be a measurable (e.g. ATP or protein levels after cleaning, disinfectant levels, flow rates, pHs, temperatures, pressures, contact times) or an observable parameter related to the control option. Where control limits are based on subjective data (e.g. visual observations) the food processor needs to provide clear guidance on requirements for compliance with practices or procedures or pictorial examples of what is acceptable (e.g. photographs to define clean surfaces or appropriate wearing of protective clothing). For the example in Table 2.4 an operating limit could be applied to a rapid assessment of the cleanliness of the wands, nozzles and tools by ATP or protein testing prior to entry.

**Table 2.4** Operational prerequisite management table as adapted from classical HACCP CCP management (Holah 2013)

Process step or area	Likely hazard	Source or contamination event vector	Control measure(s)	Operating limit(s)	Verification(s)	Corrective action(s)	Records
Milk spray drying	<i>Salmonella</i>	Removal, cleaning and reinsertion of milk spraying nozzles	(1) Spray dryer processing are air filtered to 95% removal of 1.0µm particles	ATP <150RLU	(1) ATP assessment of the cleaned wand and nozzle.	(1) Staff retraining	(1) Dryer intervention record including correct observation of removal and reinsertion procedure
			(2) Gloves are worn by operatives to remove and replace nozzles		(2) Visual assessment of the removal and reinsertion procedure	(2) Revue of wand, nozzle, tool and spray dryer contact surface cleaning	(2) Post-decontamination RLU values
			(3) Nozzles and support wands are removed and replaced by an alcohol decontaminated blanking plate		(3) Occasional microbiological verification of wand, nozzle, tool and spray dryer contact surface cleaning		(3) Post-decontamination microbiological values
			(4) Nozzles cleaned and covered with plastic bag until reinsertion				(4) Tamperproof identity tag number
			(5) Glove and plastic sleeve change by operatives prior to reinsertion				
			(6) ATP assessment of cleaned nozzles. If RLU value <150, nozzles inserted (otherwise re-cleaned)				
			(7) Use of dedicated tools				
			(8) Alcohol decontamination of gloves, sleeves, nozzles, wands, tools and spray dryer contact surfaces				
			(9) Blanking plate removal and nozzle reinsertion				
			(10) Tamperproof tag installed				

**2.7.11 Step 11: establish a monitoring system**

Monitoring systems describe the methods by which the food processor ensures that the OPs are operating within their defined control or operating limits and are thus 'in control' and, as a corollary of this, produces an accurate performance record that can be used for process verification (Stage 13). The monitoring system must be able to detect loss of control at the OP in a time frame to provide corrective action to regain control of the OP.

Monitoring systems should ideally be on-line and could include air and gas pressure, humidity, temperature, chemical concentration, redox, conductivity or pH probes; UV intensity, flow rate, and rapid hygiene checks such as ATP, allergen and protein tests. Other monitoring checks may be visible and could include an assessment of cleanliness, an assessment of a personnel clothing changing procedure or whether a procedure is correctly being followed. For the example in Table 2.4, during the nozzle removal procedure, observations could be made to ensure that the procedure was being undertaken correctly and that there were no extrinsic factors that could act as additional contamination vectors.

**2.7.12 Step 12: establish a corrective action plan**

Practical and achievable corrective actions to be undertaken when the results of monitoring at an OP detect a situation where a control limit has not been met (deviation) or when a treatment system is drifting out of control, should be specified. Responsibilities for corrective actions should be clearly defined and all relevant personnel should be trained and competent. For the example in Table 2.4, corrective actions would review the training of the staff against removal and re-installation procedures and the effectiveness and validation of the tools and cleaning equipment decontamination programmes.

Any product that could have been contaminated through any loss of control should be placed on hold following company quarantine procedures to allow authorised personnel to determine its fate. The cause of the deviation should then be investigated and appropriate remedial action taken, such that the OP will be returned to control. Further steps must then be taken to ensure that the same issue cannot occur in the future and the company should confirm that remedial actions have been undertaken and that they will be effective.

**2.7.13 Step 13: verification**

Verification is concerned with three activities: validation, verification and review. The objective of the validation stage is to ensure that all sources and contamination vectors for hazards that could be present in the processing environment have been considered and that the controls put in

place to reduce or eliminate them are technically sound and effective. The first stage of the validation is a desk-top activity to review the identification, selection and/or exclusion of hazards, the risk analysis of identified hazards, the appropriateness of the selected controls, the designation of controls as OPs, the suitability of their control limits and monitoring/verification methods and the adequateness of the corrective actions.

The second stage of the validation process is the validation of the identified control actions, as appropriate. In the example in Table 2.4, the efficacy of the tool and nozzle cleaning and disinfection process can be validated by undertaking the cleaning exercise a number of times and recording the level of cleanliness achieved as an ATP relative light unit (RLU) count.

Verification of the PEP gathers information from routine analytical tests that are used to demonstrate the effectiveness of the hazard controls and OPs in a time frame beyond that of monitoring (Stage 11). For example, whilst microbiological sampling of the tools and nozzles in Table 2.4 is not acceptable for monitoring of a control measure, it could be undertaken for verification purposes

Verification is also a desk-top and audit exercise to examine the entire PEP and examples of such activities include: internal auditing of OPs to establish, for example, that personnel are following the stated procedures/work instructions; external auditing programmes (supplier audits, third part audits); analysis of customer complaints; trending of monitoring and verification results and a review of any deviations, corrective actions and any resulting foodstuff disposal.

In accordance with the general principles of food-safety management, the safety of the environmental plan has to be reviewed on a regular basis and at least annually. The review should demonstrate that the plan is still relevant and that controls are working effectively. A review of the plan should also be initiated following any significant change to the food production process or the processing environment:

- Changes in the production process that affect the processes management from the processing environment, e.g. transport flows, service routes.
- Changes in factory environment, e.g. building work.
- Changes in cleaning and disinfection practices.
- Changes to production equipment and maintenance schedules.
- Changes in legislation or codes of practice relating to, e.g., control limits or methods of analysis.

#### **2.7.14 Step 14: *establish documentation and record keeping***

Accurate and efficient record keeping is essential to the successful application of the PEP. Records should be accurate, timed and dated, include the actual as well as any calculated results, signed by the individual

responsible for the assessment and by a delegated supervisor/manager who reviews the results. All records should be retained for at least the shelf-life of any foodstuffs and be sufficient to enable records to be available to support a defence of due diligence. In the example in Table 2.4, records would be kept of all interventions into the spray dryer, whether nozzle removal and re-installation procedures had been correctly followed, ATP and microbiological counts following nozzle and tool cleaning and the use of any tamperproof tag numbers.

## 2.8 Conclusion

Foods are primarily contaminated with hazards during growing and harvesting of raw materials, storage and transport to the factory and processing into finished products. The three main types of food contaminants are physical, chemical and microbiological.

Hazards in food can be managed by HACCP prerequisites, a HACCP plan and a quality management plan. To more effectively manage HACCP prerequisites, a PMP has been advocated, which comprises two elements: generic hygienic food infrastructure and practices prerequisites and specific processing environment prerequisites. Generic hygienic infrastructure and practices are indicated in Table 2.1 and are required to be implemented as best practice in all factories. The relevant chapters in this book indicate the nature of such best practice.

Environment prerequisites are unique to each factory as each factory will have unique hazard sources and vectors. The proposed PEP effectively identifies these sources and vectors for identified hazards and ensures that adequate prerequisite controls are in place. The PEP also recognises that following a hazard analysis, some controls may be critical to the safety of the food product and can be regarded as OPs. In the same way that the HACCP plan concentrates day-to-day management of the process on any CCPs identified, the PMP equally concentrates the day to day management of the processing environment on any identified OPs.

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# Hygienic factory design for food processing

J. T. Holah, Campden BRI, UK

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**Abstract:** Hygienic factory design is concerned with protecting ingredients, packaging, intermediate and finished products from contamination from the processing environment. At a building design level, this involves the provision of a series of barriers to protect the product from the external environment and non-food manufacturing activities and, within the food manufacturing environment, the segregation of incompatible ingredients, packaging, intermediate and finished products and other activities, e.g. cleaning rooms, maintenance and quality/testing activities. Hygienic factory design also focuses on the building elements (floors, walls, ceilings, windows, doors, roofs) and the service provisions (water, lighting, ventilation, electrical installations, steam, compressed air, etc.) to ensure that such structures neither form hazards themselves (e.g. foreign bodies, chemicals) nor give rise to harbourage sites for other hazards (e.g. pests or microorganisms).

**Key words:** building, segregation, high care/risk, changing rooms, roof, ceiling, wall, floor, drain, door, window, services, ventilation, water.

## 3.1 Introduction

Food factories must fulfil a variety of demands including providing an efficient manufacturing site that will allow flexible food production within a defined time frame (e.g. 5–10 years) whilst obeying local planning laws on building aesthetics and national building regulations. All factories, however, must produce safe food products, and hygienic factory design is undertaken to provide the following:

- A defence against external factory hazards. These could be micro-organisms, pests, unauthorised human access, airborne chemical taints and airborne particulate matter.
- A defence against internal factory hazards. These could include non-food production activities such as engineering workshops and boiler

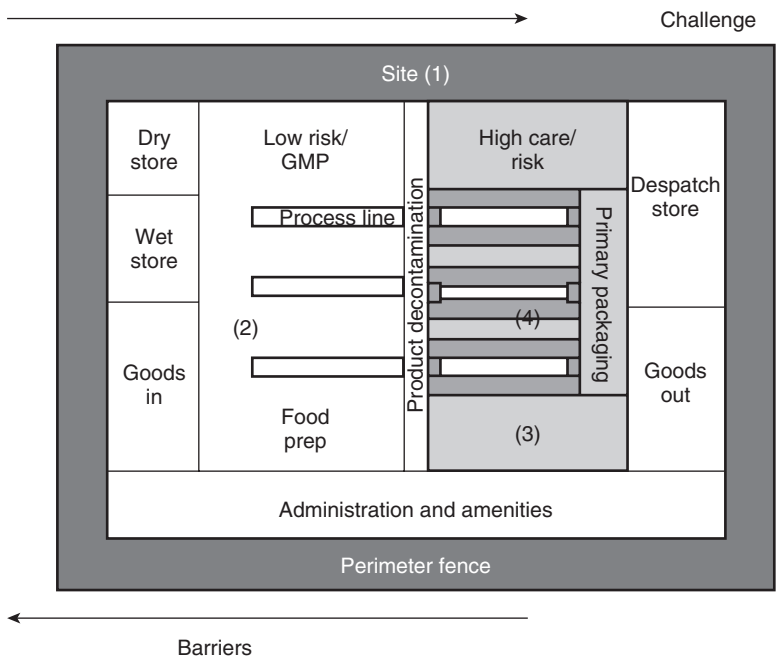
rooms, microorganisms from raw materials, allergens, water and taints from certain ingredients.

- Internally, the factory should be designed to not harbour any hazards that can enter the factory and to be cleanable such that hazards can be easily removed.
- Sufficient space for the placement of equipment and storage of materials, to allow the hygienic performance of all operations and to facilitate cleaning and maintenance.
- Internal flows of people, product, packaging, air and wastes that prevent cross-contamination.
- Suitable environmental conditions (temperature, humidity) to maximise and maintain the organoleptic and food safety qualities of the raw materials, intermediate and finished products.
- Security against deliberate contamination.
- The maintenance of hygienic building fabric conditions via structural rigidity limiting building movement. This is undertaken by consideration of appropriate foundations, steelwork and floor slabs.
- The maintenance of hygienic building fabric conditions via the use of building materials with long-term durability, or materials that can be easily replaced or repaired.
- Compliance with customer/Global Food Safety Initiative (<http://www.mygfsi.com/>) GFSI best practice.

With the increase in the number of ready-to-eat (RTE) food products on the market, perhaps the most important of these hygienic design requirements is the protection of the food product from microbial cross-contamination, particularly following the final product decontamination step. Factories should be constructed as a series of barriers that aim to limit the challenge of contaminants. The number of barriers created will be dependent on the nature of the food product, established from the hazard analysis critical control point (HACCP) study, and each barrier should reduce the challenge of a hazard to the subsequent barrier. Figure 3.1 shows that there are up to four levels of segregation that are typical for food plants. Whilst these barriers were primarily conceived to control microbiological contamination in the chilled RTE product sector, they are also effective at controlling many other hazards.

Level 1 represents the siting of the factory, the outer fence and the area up to the factory wall. This level seeks to control the degree of challenge of a hazard to the factory interior. This may be, for example, by reducing the number of pest harbourage areas, controlling pest access to waste materials, the downwind siting of effluent plants and the control of unauthorised public access.

Level 2 represents the factory wall and other processes (e.g. UV flytraps) that should separate the factory from the external environment (e.g. prevailing wind and surface water run-off). Level 2 also includes all internal



**Fig. 3.1** Schematic layout of a factory site showing ‘barriers’ against contamination: (1) perimeter fence, (2) main factory buildings, (3) walls of high-risk area, (4) product enclosure within high risk.

barriers designed to separate production stages (raw materials, intermediate product, finished product, packaged product), incompatible materials (wet, dry, chilled, frozen, allergenic, vegetarian, organic, genetically modified (GM) materials, kosher or halal, packaging) and non-food production areas (engineering, boiler rooms, cleaning stores, changing areas etc.). The food production area may be split into a ‘dirty’ area, e.g. where animals are slaughtered or the soil is washed from vegetables and a ‘clean’ area, handling prepared food ingredients.

Level 3 represents the internal barriers that are used to separate manufacturing processes of different microbiological risk, e.g. pre- and post-heat treatment. Product in level 3 will have a lower microbiological count than in level 2 and the microbial reduction process, incorporated as the barrier between level 2 and 3, may be a simple decontamination process (e.g. produce washing) or a pasteurisation treatment (e.g. an oven, kettle, fryer or heat exchanger). Such separation, which creates zones usually referred to as high-care or risk areas, should seek to control the air, people and surfaces (e.g. the floor and drainage systems and the passage of materials and utensils across the barrier).

Level 4 represents a product enclosure zone, set within the level 3 high-care/risk area. A product enclosure zone could encompass true aseptic filling

or 'ultra-clean' processing and packing areas such as glove boxes or the use of highly filtered air as a barrier around the process line.

The information in this chapter has been established from industry best practice and also incorporates the requirements of American and European legislation and standards, and retailer requirements expressed through the GFSI.

### **3.2 Design, construction and maintenance of the site**

Attention to the design, construction and maintenance of the site surrounding the factory provides an opportunity to set up the first (outer) barrier to protect production operations from contamination. The focus on the site barrier has changed over the last 20 years or so from consideration of pests and the protection from environmental conditions, e.g. prevailing wind and surface water run-off, through the control of unwanted access by people, to the threat of bioterrorism.

Whenever possible, factories should be located away from:

- environmentally polluted areas and industrial activities that pose a serious threat of contaminating food (e.g. objectionable odours, smoke, dust or other contaminants);
- areas subject to flooding unless sufficient safeguards are provided;
- areas prone to infestations of pests;
- areas prone to excessive levels of airborne bacteria, yeasts and moulds;
- areas where wastes, either solid or liquid, cannot be removed effectively.

At the site level, a number of steps can be taken to control hazards including the following:

- Have clearly defined boundaries, e.g. a perimeter fence or wall, with controlled access to the factory grounds to keep out animals or unauthorised persons.
- Measures to maintain site security, including the use of gate houses, security patrols and maintenance schedules for barrier fencing or other protection measures.
- The use of two lines of rodent baits, one against the external fence and one against the factory walls, located every 15–21 m (45–65 ft) along the perimeter boundary fencing and at the foundation walls of the factory, together with a few mouse traps near building entrances is advocated by Imholte (1984).
- Have adequately draining areas or installed external drainage that should not pass under processing areas. The drainage system must be sufficient to handle peak volumes of rainwater without the possibility of leakage from manhole covers, etc.
- Open waterways can attract birds, insects, vermin, etc., and should be enclosed in culverts if possible.

- Be sealed or otherwise surfaced, drained and graded. The provision of lawn and landscaping is effective for sealing large non-traffic areas.
- Have roadways of a dense, hard, compacted and dust-sealed material (e.g. concrete, asphalt, paving) suitable for wheeled traffic.
- Have roadways with suitable slopes to prevent accumulation of water.
- Have well-planned and properly maintained landscaping of the grounds which can assist in the control of rodents, insects and birds by reducing food supplies and breeding and harbourage sites. In addition, good landscaping of sites can reduce the amount of dust blown into the factory.
- Landscaping is a balance between controlling hazards and making the site attractive to the local community and auditors, and is likely to be country dependent. Small shrubs may be acceptable but trees, particularly those bearing fruits and berries, may not be.
- As part of the site landscaping, trees should be avoided. If necessary for screening or wind reduction, tree species should be chosen that reduce bird roosting and should be planted at least 9–12 m (30–40 ft) away from buildings (Graham, 2005).
- An area of at least 1 m and preferably 3 m immediately adjacent to buildings should be kept free of vegetation and covered with a deep layer of gravel, stones, paving or roadway, etc. (Katsuyama and Strachan, 1980; Troller, 1983). This practice helps weed control, assists inspection of bait boxes and traps and helps maintain control of the fabric of the factory building.
- Some flying insects require water to support part of their life cycle, e.g. mosquitoes, and experience has shown that where flying insects can occasionally be a problem, all areas where water could collect or stand for prolonged periods of time (waterways, old buckets, tops of drums, etc.) need to be removed or controlled.
- Storage of equipment, utensils, pallets, etc., outside should be avoided wherever possible as they present opportunities for pest harbourage. Wooden pallets stacked next to buildings are also a known fire hazard.
- Entrances that have to be lit at night should be lit from a distance with the light directed to the entrance, rather than lit from directly above. This prevents flying insects being attracted directly to the entrance.
- All waste containers should be lidded to prevent attraction to pests and any spillages should be cleared up as soon as possible.
- Processes likely to create microbial or dust aerosols, e.g. effluent treatment plants, waste disposal units or any preliminary cleaning operations, should be sited such that prevailing winds do not blow contaminants directly into manufacturing areas.
- Have adequate facilities for the disposal of effluent and/or the establishment of an effluent treatment plant in such a location in relation to the prevailing wind and at such a distance (as far as is practicable

within the site boundary) as to avoid pollution of processing and storage areas.

- Siting of raw materials, process steps or finished products outside the protection of factory buildings is not desirable as this may increase the chance of product adulteration. Similarly, the siting outside of the factory buildings of storage facilities, e.g. silos, water tanks, and packaging stores should be avoided wherever possible. If not possible, they should be suitably locked so that people or pests cannot gain unwanted access to food materials.
- Equipment necessary to connect transport devices to outside storage facilities (e.g. pumps, pipes, augers, conveyors, discharge tubing and fittings between tankers and silos) should be locked away when not in use.
- Parking areas for visitors and staff should not be close to factory entrances and external food storage areas.
- Site lighting at night should be sufficient to monitor external plant areas effectively. This will clearly be a compromise as additional lighting will attract insects and perhaps annoy neighbours. Motion detectors could also be considered.

### 3.3 Building structure

The building structure is the second and a major barrier, providing protection for raw materials, processing facilities and manufactured products from contamination or deterioration. Protection is both from the environment, including rain, wind, surface runoff, delivery and dispatch vehicles, dust, odours, pests and uninvited people, etc., and internally from microbiological hazards (e.g. raw material cross-contamination), chemical (e.g. cleaning chemicals, lubricants) and physical hazards (e.g. from plant rooms, engineering workshops).

It is the responsibility of factory management to ensure that all hazards in the environment surrounding the factory are recognised (e.g. waste water treatment plants, farms, heavy chemical industries, rivers, canals, ponds, marshes) and that the site and, more importantly, the factory envelope prevent these hazards from contaminating the food product. This will relate to the design of the factory shell, the siting of factory entrances with respect to the predominant wind direction, the internal floor levels with respect to the outside ground level and the factory air filtration systems.

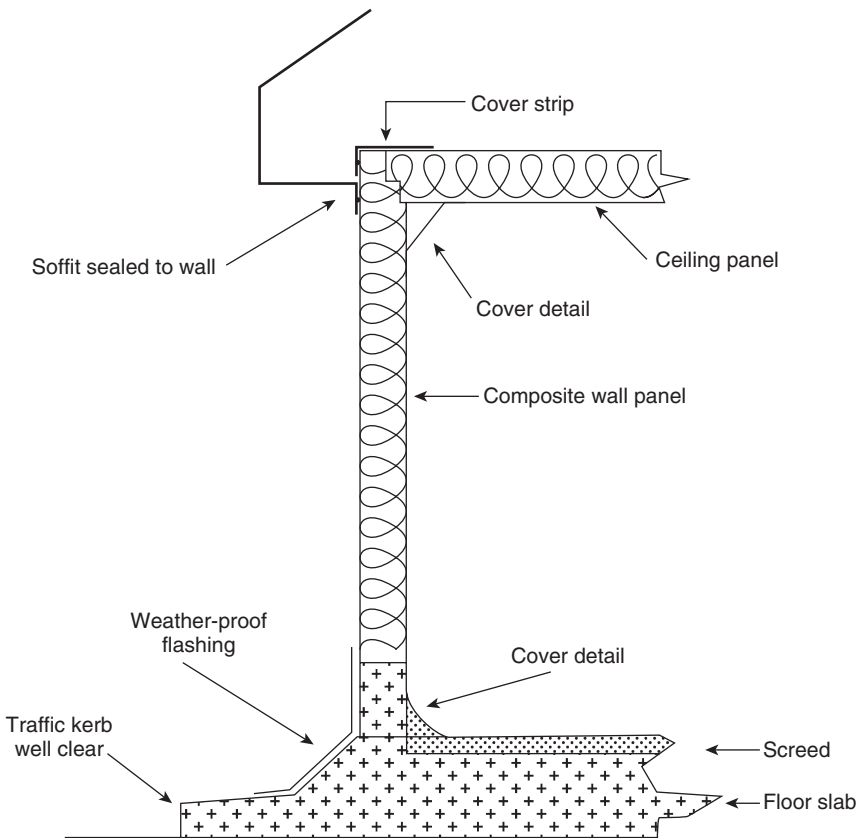
With respect to the protection of hazards from the external environment, the design of the basic factory shell should consider the following:

- Preventing direct access into the factory at ground floor level reduces the challenge of environmental contamination (mud, soil, foreign bodies, etc.), particularly from vehicular traffic (forklift trucks, raw



material delivery, etc.), to food processing operations. This can also act as a barrier to pathogenic microorganisms typically found in the environment, particularly *Listeria* spp., *Bacillus* spp., *Campylobacter* and *Clostridia* spp. and to a lesser extent *Salmonella* spp. and *Escherichia coli*.

- To facilitate this, the internal factory floors should be higher than the outside ground levels (Fig. 3.2) such that there is a physical barrier to traffic (personnel and vehicular). The internal floor level may only be a few cm (inches) above outside ground level or, typically in modern factories, at the height of the loading dock. External vehicles have thus to place their load onto the internal floor as they cannot access the factory. In older factories which have a common ground/floor level, plinths of approximately 15cm (6in) in height and just over a pallet width in depth, can be built at factory entrances which prevent the entry



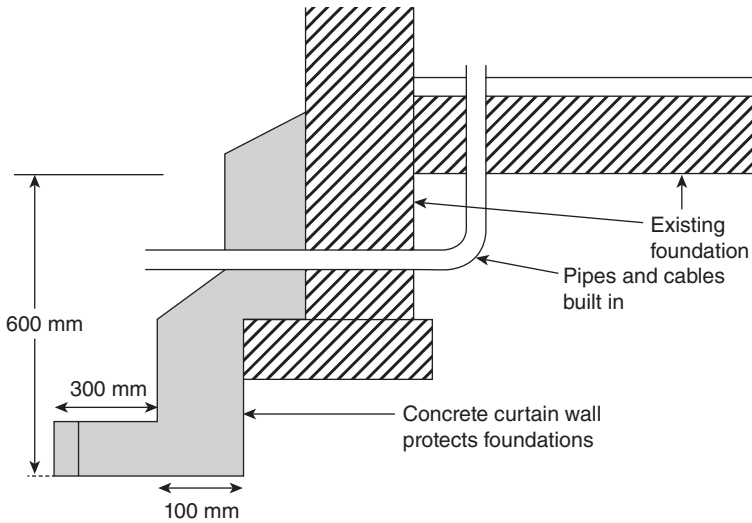
**Fig. 3.2** External wall construction to act as a barrier to external contamination and to facilitate docking, etc., for the movement of goods to the factory interior, (note: the diagram illustrates floor levels only, not necessarily wall or ceiling design).

of, for example, forklift trucks, only allowing them to deposit their load on the plinth.

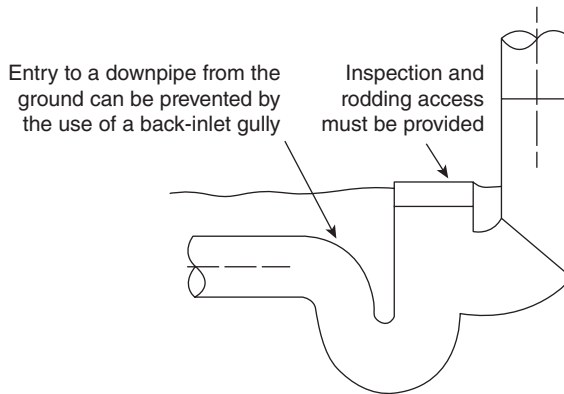
- Differential factory and external floor levels also control the potential for flooding. In addition, the factory building may often be placed on the highest point of the site to further reduce the chance of ground level contamination from flooding.
- The siting and construction of factory openings should be designed with due consideration for prevailing environmental conditions, particularly wind direction and drainage falls. Factory air intakes should be appropriately located with respect to prevailing wind direction, and high-risk air intakes should not be downstream of low-risk air extracts.
- Openings should be kept to a minimum and exterior doors should not open directly into production areas. External doors should always be shut when not in use and if they have to be opened regularly, should be of a rapid opening and closing design.
- All openings to the outside should be provided with solid doors or protected, glazed windows.
- There should be one entrance only to the food production areas. To facilitate this, the factory should be designed such that delivery drivers can talk to warehouse/despatch personnel without needing to enter the factory or use the factory facilities. This serves two purposes. Firstly, it prevents operatives moving directly from the factory interior to the outside of the plant, and vice versa, which limits the transfer of contamination from the building exterior. Secondly it fosters a 'you are now entering a food factory' mentality on food operatives, which may influence their hygienic behaviour. Identity cards which double as door keys are optional, but can also be used to gain entrance to internal higher hygiene zones.
- Prevent entry of contaminants and pests, e.g. no unprotected openings and the roof, walls and foundations are maintained to prevent leakage. Attention should be given to non-draining flat roof areas, joints around services, rain guttering and drainage, seals between floors in multi-storey units and seals between old and new buildings.

In some older buildings, the foundations may be too shallow (some rodents can burrow over 1 metre vertically) and will not prevent rodents from burrowing underneath. In these cases it is recommended that a curtain wall is built against the existing outside walls or footings to a depth of at least 600mm below ground level with a bottom member turned outwards from the building to a distance of 300mm to form an 'L' shape (Fig. 3.3).

All points where cables, drains and services pass through foundation walls and floors must be sealed. Drains and sewers must be proofed and regularly maintained to prevent rodents gaining access and using them as harbourage or as a means of entry to buildings. Any defective drains must be located and repaired. Inspection chambers, covers, hatches and rodding



**Fig. 3.3** Design of foundations for the exterior walls of a food processing plant (from Timperley, 2003).



**Fig. 3.4** Back-inlet gully to prevent pest access by rodents through pipes (from Timperley, 2003).

caps must be inspected regularly and all disused lengths of drain either filled with concrete to the connection with the sewer or collapsed and the trench filled with dense hardcore. Any storm water drains should be protected with top-hung flaps and maintained regularly to remove silt and leaves. Back inlet gulleys can be used to prevent rodents from entering and climbing the inside of rainwater pipes at ground level (Fig. 3.4). If these are not fitted, then rodent access can be controlled by means of wire mesh balloons fitted to the outlet from the gutter. Rodents are able to squeeze through small holes in order to gain access to buildings. A small rat can squeeze through a 10 mm crack and a mouse through one of 6 mm. These balloons, therefore,

must have a mesh size of less than 6 mm and should also be fitted at the top of any soil or ventilation pipes. Wire mesh should not be used at the bottom of downpipes because of the risk of blockage. External climbing of downpipes by rodents can be prevented by fitting flat or cone-shaped guards. These should be sited high enough to clear vehicular or pedestrian traffic but not above the level of any sills, mouldings or branch pipes which may provide alternative routes into the building.

Good hygienic design also helps prevent contamination of the food product from internal sources of contamination. Key hygienic design factors include the following:

- Wherever possible, buildings should be single storey or with varying headroom featuring mezzanine floors to allow gravity flow of materials, where this is necessary (Imholte, 1984). This prevents any movement of wastes or leaking product moving between floors.
- Whilst ideally the process line should be straight, this is rarely possible, but there must be no backtracking or cross-overs and, where there are changes in the direction of process flow, there must be adequate physical barriers. Adequate chilled storage provision must be made, particularly in high risk, to ensure product safety in the event of line stoppage, etc.
- The layout should also consider that provision is made for the space necessary to undertake the process and associated quality control functions, both immediately when the factory is commissioned and in the foreseeable future. In addition to process areas, provision may have to be made for a wide range of support activities including raw material storage; packaging storage; water storage; wash-up facilities; plant room; engineering workshop; cleaning stores; microbiology, chemistry and quality control (QC) laboratories; test kitchens; pilot plant; changing facilities; restrooms; canteens; medical rooms; observation areas/viewing galleries and finished goods dispatch and warehousing.
- Physical internal separation by walls between departments in which edible (e.g. food products and other food ingredients) and non-edible materials (e.g. boiler rooms, workshops, machinery rooms, living accommodation) are handled should be provided.
- Physical internal separation by walls between departments in which edible (e.g. food products and other food ingredients) and with any area in which gas, fumes, dust, soot deposits, offensive odours or any other impurity is present should be provided.
- All food processing operations should be carried out in a way in which the risk of contamination of one product or material by another is minimised. Contamination may be reduced by manufacturing in separate locations/factories, by separation of operations within the same factory, by enclosed systems, by partition, by air flow, by time with effective intermediate cleaning and, where appropriate, disinfection or other effective means.

- Production areas where processed foods are exposed should be physically separated, where possible, from areas where unprocessed or partially processed food is stored, prepared or handled and from non-processing areas such as laboratory and maintenance areas.
- Wet/dry area segregation must be applied when the presence of water in the factory environment would significantly increase the risk of pathogen proliferation and thus increase the risk of product contamination via the environment.
- Segregation (and colour coding) of allergen-containing products during storage and production and packing is essential. This may also apply for other identity preserved materials, e.g. generically modified organisms (GMOs).
- Microbiology laboratories, particularly those undertaking pathogen testing, shall be physically separated from production areas (and from other laboratory areas). Microbiology laboratories must have separate air and effluent discharges and safe solid waste discharge.

The design and layout of rooms should permit good food hygiene practices, including protection against contamination between and during operations. Hygienic room design should:

- protect against the accumulation of dirt and the shedding of particles into food;
- protect against contact with hazardous materials, dirt, dust, fumes, smoke and other contaminants;
- protect against the formation of condensation (humidity control) or undesirable mould growth on surfaces;
- permit adequate cleaning and/or disinfection and maintenance;
- permit immediate drying after cleaning and disinfection;
- provide adequate lighting and ventilation.

Specific rooms should be considered for, for example, label and package printing, QC stations, maintenance and equipment repairs, staff facilities, first aid facilities, laboratories.

Access of personnel and visitors should be controlled. Designated walkways should be provided and marked in internal and external areas such that by simple logical routes, the traffic pattern of personnel (and vehicles) should prevent cross-contamination of the product. Manufacturing areas should not be used as general rights of way for personnel, or materials or storage.

### **3.4 High-care/risk areas**

Where product decontamination (cooking, washing) and further processing of foods is undertaken, the building design and process flow layout must be organised so that there is no possibility of cross-contamination. The

preparation, decontamination and post-decontamination processing of product (particularly those products susceptible to microbial growth) must take place in separate rooms. All areas in which preparation prior to the decontamination process is undertaken, and in which operations are performed after the product has been packed in its initial packaging, are usually referred to as low-risk areas. All areas in which operations undertaken after the decontamination process and prior to the product being packed in its initial packaging, are usually referred to as high-hygiene or controlled areas.

In the dry foods industry, such zones have been termed the Primary Salmonella Control Area (GMA, 2009). In the chilled, RTE sector such zones are classified as high-care or risk areas. High-risk areas process products that have received a pasteurisation process (6 log reductions of microorganisms) via a heating process and are designed to prevent cross-contamination. High-care areas process products that have received less than a pasteurisation process (typically a 2 log reduction, e.g. produce washing) and are designed to minimise cross-contamination. The decontamination process forms the barrier between the low and high-risk areas.

Controlled or high-hygiene areas, hereafter referred to as high-risk areas, shall be fabricated and designed to a high standard of hygiene and:

- be physically separated from low-risk food processing areas;
- be serviced by staff dedicated to that function only and who enter the high-risk area via separate changing room facilities or a buffer area;
- have low/high-risk transfer points, the location and practices of which shall not compromise product contamination;
- be serviced with segregated (colour coded) equipment, utensils and cleaning equipment;
- be as small as possible as their maintenance and control can be very expensive (to reduce costs, particularly for any heating, ventilating and air conditioning (HVAC) system).

The design of the high-risk food processing area must allow for the accommodation of five basic, primary requirements, i.e.

- processed materials and possibly some ingredients;
- processing equipment;
- staff concerned with the operation of such equipment;
- primary packaging materials;
- finished products.

All other secondary requirements should be considered as unnecessary and, to reduce the number of potential environmental niches for microorganisms wherever possible, should be kept out of the high-risk processing area. These secondary requirements include:

- structural steel framework of the factory;
- service pipework for water, steam and compressed air; electrical conduits and trunking; artificial lighting units; and ventilation ducts;
- compressors, refrigeration units and pumps;
- maintenance personnel associated with any of these services;
- ‘furniture’ and computers, etc., associated with office facilities.

### 3.5 Storage areas

Adequate product loading and unloading facilities must be provided and must also be sealed and protected from the weather by covered bays, an awning or other suitable means. For refrigerated products, the loading and unloading bays shall be designed to allow transfer of products between the cold store and the refrigerated vehicle with the least exposure to ambient temperature and with the least possible handling. Loading docks should be above ground level. Loading docks that are sunk into the ground should be avoided as they are difficult to drain and clean. A 50 cm (20 in) deep smooth strip of material, e.g. stainless steel, should be installed under the dock wall overhang to prevent rodent access (Graham, 2005).

Storage rooms must be available for the hygienic handling and separation of food, ingredients, packaging and hazardous chemicals. Finished product should be stored separately from raw and processed ingredients and handled under conditions to minimise damage, deterioration and prevent contamination, e.g. by thermophilic spoilage, rusting or corrosion. Dry stores must be located away from wet areas and segregation of allergen-containing products during storage is recommended. The need for deboxing-debagging areas for the removal of external packaging should be considered.

Sufficient refrigeration capacity must be available to chill, freeze, store chilled or store frozen the maximum anticipated product throughput with allowance for periodic cleaning of refrigerated areas and to maintain product temperatures within specification under worst case ambient temperature.

Each freezer and cold storage compartment used to store and hold food (and any heating facilities) capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature measuring device or temperature recording device and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

Cold store walls shall be effectively insulated to prevent condensation on the external side of the walls. Freezers, cold rooms and chillers are normally constructed of prefabricated wall and ceiling sections with internal lining finishes constructed of anticorrosive materials with a smooth, light coloured finish. Refrigerated stores should be fitted with an air lock, an air

curtain or a plastic door or curtain to prevent a rise in temperature within the store when external doors are opened. Thawing of product must be undertaken in equipment and rooms designed for the purpose. Refrigeration and freezing equipment must be installed in a room separate from food handling, processing and storage areas.

Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination. Storage tanks, bins and silos shall be constructed of suitable materials and be fitted with suitable, close fitting covers and, if vented, the venting shall be designed and maintained so as to not contaminate the contents. The air venting arrangements of tanks and silos should be microbiologically and pest filtered as appropriate. If necessary, dehumidifiers should be fitted to control condensate formed during external temperature cycling.

Packaging materials should be stored in a designated, dry area separate from raw materials and finished product, and in such a manner that the packaging is not exposed to a risk of contamination. Wherever possible, primary packaging materials should be stored separately from secondary packaging materials.

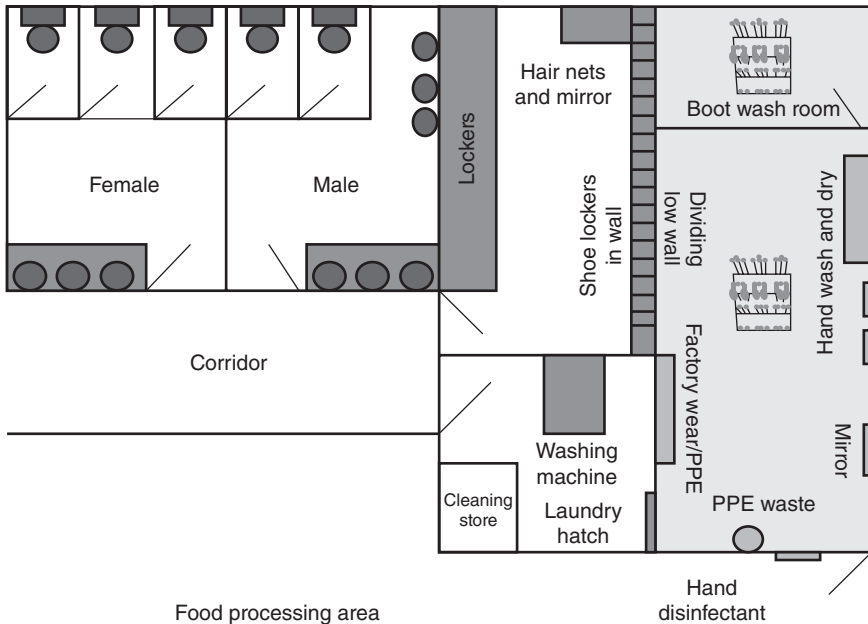
Food premises must have adequate storage facilities for the storage of items that are likely to be a source of contamination to food including chemicals, clothing and personal belongings. Storage facilities must be located where there is no likelihood of stored items contaminating food or food contact surfaces.

### 3.6 Personnel areas

Personnel hygiene facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. A simple changing room layout is shown in Fig. 3.5, which illustrates a number of good practice points. These include the following:

- Toilets are placed before the changing area. This is undertaken to ensure that food operatives only go to the toilet whilst wearing their street clothes.
- On arriving at work, food operatives are likely to have contaminated clothing, footwear and hands, with such contamination having arisen from the home and the journey to work. On entering the changing area outer street clothing is removed and street footwear is placed in racks in a boundary wall or bench. Hairnets can be donned at this point so that loose hairs are not dislodged on the food manufacturing side of the barrier.
- Operatives then step over the bench and immediately wash their hands. The three primary routes of staff external contamination (clothes, footwear and hands) have now been controlled.





**Fig. 3.5** Basic layout of a changing room area that aids hazard removal from food operatives as they enter a separate, distinct, food processing area (PPE = personal protective equipment).

- Operatives then put on factory clothing and footwear.
- Operatives then enter the food manufacturing area via a hand disinfection station, usually an alcoholic hand rub.
- At the end of the work period, operatives enter the changing area and discard their factory clothing and footwear. Clothing can enter a laundry room whilst footwear remains captive to the food production area and is cleaned and disinfected in a separate area.
- Operatives step over the barrier, change into their street clothing and then use the toilet facilities, go to the canteen or rest area or leave the building, etc.
- The wall or barrier thus defines the start of the food manufacturing area and, through only wearing factory clothing past this point, reinforces personnel hygiene requirements and prevents cross-contamination from non-food production areas.

In more specific detail, the changing room arrangements should provide an adequate number of flush lavatories connected to an effective drainage system. An example of the number of lavatories (toilets, sanitary conveniences) that should be available is given in Table 3.1. Lavatories are not to open directly into rooms in which food or packaging is handled, nor into restrooms or changing rooms. Toilets should be connected only via a

**Table 3.1** Suggested number of lavatories, urinal stalls and hand wash basins per number of staff employed

Staff number	Number of sanitary conveniences				
	Men			Women	
	Lavatories	Urinals	Wash basins	Lavatories	Wash basins
10	1	1	1	1	1
20	1	2	2	2	2
40	2	3	2	3	3
60	3	3	2	4	4
80	4	4	3	6	5
100	4	4	3	8	6
120	5	5	4	9	7
140	5	5	4	10	8
180	5	6	5	11	8
	Add 1 lavatory, 1 urinal and 1 wash basin for every 70 persons in excess of 280 persons			Add 1 lavatory, and 1 wash basin for every 35 persons in excess of 280 persons	

properly ventilated lobby with self-closing doors and there shall be at least one dedicated washroom separating the toilet and other connecting area. Essentially, after using the toilets, there should always be two hand washes prior to re-entering production areas; one within the washroom and one at the entrance to the production area. No toilet facilities, other than hand wash basins, shall be located in high-risk food production areas.

Sanitary conveniences must have adequate natural or mechanical ventilation. Ideally, toilets should be under negative pressure with an air removal rate of 1 m<sup>3</sup>/min for each toilet and urinal (Katsuyama, 1993).

An adequate number of permanently installed wash basins must be available and designated for washing hands. Wash basins must be:

- suitably located, e.g. at each entry point to the processing area, and if there are toilets, immediately adjacent to the toilets or toilet cubicles;
- of a size that allows easy and effective handwashing but discourages washing of other items, and constructed out of stainless steel or other non-corrodible material;
- fitted flush to the wall (with no crevices) or set at least 5 cm away from the wall to facilitate cleaning;
- fitted with trapped waste pipes leading directly to drain;
- provided with hot and cold running water, with mix valves as appropriate, materials for cleaning hands and for hygienic drying;
- knee, foot, elbow or automatically (hand contact-free) operated.

Whilst disposable paper towels, high-velocity and hot air dryers are acceptable for drying hands, reusable or multiple use towels should not be used.

Where necessary, the facilities for washing food, equipment, utensils and containers shall be separate from the handwashing facilities. Ideally, personnel entrances to processing areas should have two doors (that do not require the use of hands to open) with a lobby between the doors containing handwashing facilities.

Adequate changing facilities for personnel are to be provided of a sufficient size to allow the storage of personnel effects and street clothing. In addition to toilet and handwashing facilities, personnel should have access to showers where appropriate. Changing facilities should be sited to allow personnel direct access to the production, packing or storage areas without recourse to any external areas wherever possible.

The overall design philosophy of the changing facilities or washroom area should facilitate cleaning. The washroom should have at least one floor drain, to which the floor is sloped to (Graham, 2005) and toilet bowls, urinals and handwash basins should be ceiling or wall hung.

Changing facilities for personnel are to be provided when moving from one risk area to another. Wherever possible, personnel should change footwear rather than use footbaths as footbaths can be a contamination risk if not adequately controlled.

Suitable staff facilities (e.g. canteen, restroom, lunch room) shall be provided and shall not lead into the processing area directly. Where catering facilities are provided, they shall be designed and suitably controlled to prevent contamination of the food product.

Where provided, designated smoking areas shall be isolated from production areas to an extent that smoke cannot reach the product.

### **3.7 Cleaning facilities: food, equipment and chemicals**

Adequate facilities must be provided, where necessary, for the cleaning, disinfection and storage of working utensils and equipment. Such facilities should be adequately separated from food storage, processing and packaging areas to prevent contamination and be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.

Cleaning agents and disinfectants must be stored separately, in clearly identified containers, from areas where food is handled. A separate lockable area inside a food handling, ingredient or packaging store is not acceptable.

Non food chemical stores should:

- be sound, dry, well ventilated, frost proof, have ease of access and have sufficient light to enable the operator to read the label;

- be designed so that drainage from this area must be contained in the event of a hazardous spill;
- be secure (lockable), with controlled access.

Separate cleaning areas/facilities should be available for each hygiene zone. High-risk cleaning rooms should be totally segregated from the production area such that wet cleaning operations can be undertaken in a washroom in a way that minimises product contamination. The siting of the washroom on an external wall to facilitate ventilation (of condensate) and chemical supply is preferred. The washroom should have its own drainage system that, in very wet operations, may include barrier drains at the washroom entrance and exit to prevent water spread from the area. The wash area should consist of a holding area for equipment/utensils awaiting cleaning, a cleaning area for manual or automatic cleaning (e.g. traywash) as appropriate, and a holding/drying area where equipment can be stored prior to use. Air extraction and make-up may be required to prevent the build-up of condensation in the washroom.

Adequate provision is to be made, where necessary, for washing food that is separate from handwashing and equipment washing. Every sink or other facility provided for the washing of food is to have an adequate supply of hot and/or cold potable water and be kept clean and, where necessary, disinfected.

### 3.8 Roofs

Roofs have been implicated in a number of food contamination events, particularly due to *Salmonella*, as this organism can be found in the droppings of birds, attracted to the roof for food and roosting opportunities. The organisms can then enter the factory via leakage channels through the roof directly or via leaking internal down pipes. Access to external roofs and structures should, therefore, be from outside the plant.

Good hygienic design of roofs includes the following:

- Roofs shall be self-draining.
- Roofs should consist of a single membrane wherever possible.
- Roofs should be pitched to the external walls. Valley roofs, in which a roof drain is required to run across the food processing area (below) to the external walls, are not recommended.
- All roof drains should be external to the building wherever possible.
- Exhaust extracts from food processes can discharge food particles onto the roof and should be avoided as the food debris can attract birds and other infestation.
- Roofs should be designed to minimise the potential for birds, particularly seagulls, to perch.

- All openings to the roof should be curbed and flashed to a height of 0.3m (12 inches) or more (Imholte, 1984). This height may be higher subject to local regulations concerning snow fall.

### 3.9 Floors

The floor forms the basis of the entire processing operation, and a failure in the floor often results in lengthy disruptions of food production while repairs are carried out. Unsatisfactory floors increase the chances of accidents, cause difficulties in attaining required hygiene standards and increase sanitation costs (Timperley, 2002). Both the physical durability and hygienic qualities have to be considered. The overall design of the floor must be such that it can be effectively cleaned and disinfected, is safe in use (e.g. antislip) and that it is stable under these cleaning regimes and to normal processing activities (i.e. does not begin to disintegrate, which may result in microbial or physical contamination of the food being processed). Guidelines for the design and construction of floors have been prepared by Timperley (2002).

Design specifications for floors should cover the following:

- The structural floor slab.
- The waterproof membrane, which should extend up walls to a height above the normal spillage level.
- Movement joints in the subfloor and final flooring, around the perimeter of the floor, over supporting walls, around columns and machinery plinths.
- Drainage, taking into account the proposed layout of equipment.
- Screeds, either to give a flat enough surface to accept the flooring or to form the necessary falls when these are not incorporated in the concrete slab.
- Floor finish, either tiles or a synthetic resin.
- Processing considerations, including the following:
  - trucking;
  - impact loads from proposed operations, and equipment and machinery to be installed;
  - degree of product spillage and associated potential problems with corrosion, thermal shock and drainage requirements;
  - types of cleaning chemicals to be used and requirements for slip resistance.

The structural floor slab (i.e. the base on which the top layer of flooring will sit) should be capable of withstanding all structural, thermal and mechanical stresses and loads which will occur during service, as a failure will compromise the hygienic properties of the top-layer flooring. In

particular, allowances should be made for expansion, contraction and cracking, and where appropriate for problems arising from hydrostatic pressure and rising damp, which can cause the adhesion between the floor slab and flooring to fail.

All wet- or corrosion-resistant floorings need to be laid on a waterproof and acid-resistant membrane. This is particularly important in the design of suspended floors, where deflection due to heavy moving loads may cause cracks or fissures through which corrosive liquids (or water during cleaning operations) might pass to damage the structural concrete. Some of the main requirements of the membranes are that they should be:

- resistant and impermeable to specified liquids (depending on factory use);
- continuous;
- strong enough to support imposed loads and resist damage during flooring repairs;
- capable of flexing;
- extended up the walls to a height above the normal spillage level;
- carried over plinths or kerbs, below drainage channels and into drains.

The flooring material itself can be made of a number of different substances. Although concrete is resistant to chemical attack from alkalis, mineral oils and many salts, it is attacked by acids, vegetable and animal oils, sugar solutions and some salts. It is also porous and tends to crumble under impact or when abraded. As such, it is not generally considered to be suitable as a flooring material for most food processing areas. However, it can be improved by various means so that it can be used in some food storage and access areas.

The choice of flooring surfaces can be broadly grouped into three categories:

- concretes;
- fully vitrified ceramic tiles;
- seamless resin screeds.

Concrete flooring, including high-strength granolithic concrete finishes, although suitable and widely used in other parts of a factory, is not recommended for food processing areas. This is because of its ability to absorb water and nutrients, allowing microbial growth below the surface where it is extremely difficult to apply effective sanitation programmes.

Pressed or extruded ceramic tiles are laid on sand and cement mortar-bonded to the subfloor (thin bed), or on a semi-dry sand and cement mix (thick bed). A tile thickness of approximately 20 mm will provide adequate strength with either of the bedding methods. Thinner tiles (12 mm) are used for bedding into a resin bed by a vibratory method. Tile surfaces may be smooth or studded or may incorporate silicon carbide granules to improve

slip resistance. Resin grouts should be applied at least three days after the tiles have been laid, so that water from the bed can evaporate. Joints between tiles should be as small as possible but not less than 5 mm as it may be impossible to fill the joint on deep tiles (Carpentier, 2005). The grouting material should fill the joints completely to a depth of at least 12 mm and be finished flush with the tile surface. Thinner joints (1 mm) are achieved when the tiles are vibrated into a resin bed. One advantage of tiled floors is that sections or local areas of damaged surface can be replaced and colour-matched, to maintain the overall standard and appearance of the floor.

Resin-based seamless floors offer a good alternative means of attaining a hygienic surface provided they are laid on a sound concrete base. The choice of finish can be made either from various resin-based systems (primarily epoxy or polyurethane) or from polymer-modified cementitious systems. The resin-based systems can be broadly grouped under three headings:

- *Heavy duty*: heavily filled trowel-applied systems 5–12 mm thick. Such screeds are of high strength and are normally slip-resistant.
- *Self-levelling*: ‘poured and floated’ systems applied at 2–5 mm thickness. These systems are sometimes more correctly described as ‘self-smoothing’. They generally give smooth glossy surfaces.
- *Coatings*: usually 0.1–0.5 mm thick. They are not recommended for high-risk or other production areas because of their poor durability. Failures of such floors have been associated with microbial contamination, including *Listeria monocytogenes*, becoming trapped under loosened areas where the coating has flaked.

When laying resin-based floors, all efforts should be made to maximise the de-gassing of the resin to minimise the number of small gas bubble holes present at the surface. Surface active agents can be added to decrease their formation and the mortar can be rolled with a ‘prickle’ roller to try and release trapped bubbles (Carpentier, 2005). For both tile and resin floors, ultimately, the skill of the contractors laying the floor is at least as important as the choice of topping and efforts should be made to get references from previous clients, or indeed inspect previously laid floors.

Wherever possible, floors should be specified to be non-slip and unless the surface structure is heavily embossed with valley to peak heights exceeding 3–4 mm (0.1–0.2 in), i.e. when brush bristles cannot penetrate to the bottom of the valley, has no effect on microbial cleanability. Flooring materials designed to be slip resistant may have an average peak to valley height measured in millimetres, whilst the size of imperfection that could harbour microorganisms would be measured in microns (Taylor and Holah, 1996; Mettler and Carpentier, 1998). Such micron sized holes are equally likely to be found on ‘smooth’ as ‘rough’ surfaces, and are minimised by attention to good floor laying practices. Advice on slips and trips can be

obtained from the UK Health and Safety Executive at <http://www.hse.gov.uk/food/index.htm>.

Legislation in the EU requires floors to be ‘waterproof’ or ‘impervious’ and ‘cleanable’. Taylor and Holah (1996) developed a technique to assess the water absorption of flooring materials such that materials can be accepted or rejected on any water uptake recorded. Water uptake is unacceptable because if fluids are able to penetrate into flooring materials, microorganisms can be transported to harbourage sites that are impossible to chemically clean and disinfect. Cleanability is more difficult to interpret but both Taylor and Holah (1996) and Mettler and Carpenter (1998) have proposed suitable test methods in which the cleanability of attached microorganisms is assessed. When considering the selection of flooring materials, therefore, evidence for imperviousness and cleanability should be sought.

The floor should be coved where it meets walls or other vertical surfaces such as plinths or columns as this facilitates cleaning. As part of the design of floors, allowance has to be made for adequate drainage of water – that is, the physical shape of the floor should allow water to drain away easily. A slope (or ‘fall’) of 1 in 60 is normally adequate; 1 in 40 may be required for floors that are habitually very wet, whilst 1 in 80 may be sufficient for normally dry tiled floors. Surface irregularities should be <3 mm in 3 m (0.1 in in 9.8 ft) to prevent surface pooling of liquids.

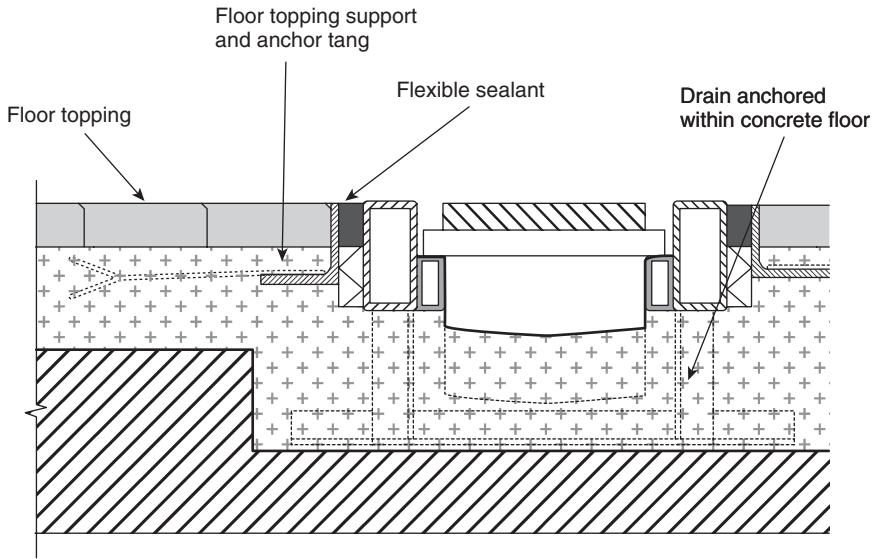
### 3.10 Drainage

Detailed consideration of the drainage requirements is an important aspect of floor design (Fairley, 2011). Ideally, the layout and siting of production equipment should be finalised before the floor is designed to ensure that discharges can be fed directly into drains. Equipment should not be located directly over drainage channels as this may restrict access for cleaning.

The type of drain used depends to a great extent upon the process operation involved but should always be large enough to carry peak flows. For operations involving a considerable amount of water and solids, channel drains are often the most suitable. Where the channels are close to a wall they should not be directly against it to avoid flooding of the wall-to-floor junction. An indirect advantage of channels near a wall is that the siting of equipment hard up to the wall is prevented, thus providing access for cleaning. For operations generating volumes of water but with little solids, aperture channel drains are more favourable (Fig. 3.6). Drainage pipes should be sized and laid to falls that are adequate to take the predicted flow loads and to achieve a velocity that is ‘self-cleaning’ (regarded as >0.75 m/s or 2.5 ft/s).

In most cases, channels should have a fall of at least 1 in 100, have round bottoms and not be deeper than 150 mm for ease of cleaning. They must be





**Fig. 3.6** Installation of a drain channel emphasising the presence of anchor tangs that are essential for providing a structure that limits movement at the surface interface of the drain channel and floor finish.

provided with gratings for safety reasons. The channel gratings must be easily removable, with wide apertures (20mm minimum) to allow solids to enter the drain.

Of particular importance is the interface between the drain channel and the floor. The edge of the channel rebate must be properly designed and constructed to protect it from movement damage, particularly if wheeled vehicles are in use, by the provision of sufficient anchor tangs (Fig. 3.6). If this is not the case, the drain/floor interface can break down and become a harbourage point for liquids and microorganisms.

The distance that fluids should have to move over flooring to fall to drain should not exceed 5–8 metres (16–26 ft). The bay size drained by gulley pots is dependent on the floor slope and the maximum thickness of screed under the floor topping and that bays of between 100 and 256 m<sup>2</sup> (1076–2756 ft<sup>2</sup>) are possible for slopes of 1 in 50 and 1 in 80 respectively. For channel drains with a channel drainage of 1 in 100, bay sizes of up to 544 m<sup>2</sup> (5856 ft<sup>2</sup>) are possible.

Separate drainage systems are preferable for each hygiene zone, but effluent flow in drains from an area of higher to lower hygiene classification is acceptable as long as there is no opportunity for effluent backflow. Ideally there should be separate low and high-risk drains running to a master collection drain with an air-break between each collector and master drain. If possible, the high-risk drains should enter the collection drain at a higher point than the low-risk drains, so that if flooding occurs, low-risk areas may

flood first. The drainage system should also be designed such that high-risk drain rodding points are outside high-risk areas. Manholes in the factory should be avoided but, if essential, shall be doubly sealed.

Solids must be separated from liquids as soon as possible, by screening (with, for example, removable sediment baskets), to avoid leaching and subsequent high effluent concentrations. Traps should be easily accessible, frequently emptied and preferably outside the processing area.

Food premises must have a sewage and waste disposal system that is constructed and located so that there is no likelihood of the sewage and waste water polluting the potable water supply or contaminating food. Effluent or sewage lines must not be connected to any other drains, should not pass directly over or through food production areas and must be directed to a septic tank or a sewerage system.

### 3.11 Walls

Hygiene standards for walls as defined in various EC directives require that they must be constructed of impervious, non-absorbent, washable, non-toxic materials and have smooth crack-free surfaces up to a height appropriate for the operations. For high-risk areas the standard of construction and finish must apply right up to ceiling level. The same hygienic assessment techniques as described for flooring materials are also directly applicable to wall coverings and finishes. Guidelines for the design and construction of walls have been prepared by Timperley (2003).

Load-bearing and fire-break walls are often constructed from brick or blockwork. Walls should be constructed with solid blockwork having no cavities. All walls that contain internal cavities (e.g. block work with open centres) or fillings susceptible to pest ingress should be capped at the base and top. The first two courses of blockwork should have their centres filled with mortar (Graham, 2005). These walls can either be directly painted with an appropriate waterproof coating or rendered with a cement and sand screed to achieve a better surface smoothness for the coating layer. The covering of walls by other materials such as sheets of plastic or stainless steel is not recommended unless the walls are absolutely flat so as to prevent the harbourage of pests, and fluids containing microorganisms, between the two walling materials.

The coating applied must result in a finish that is:

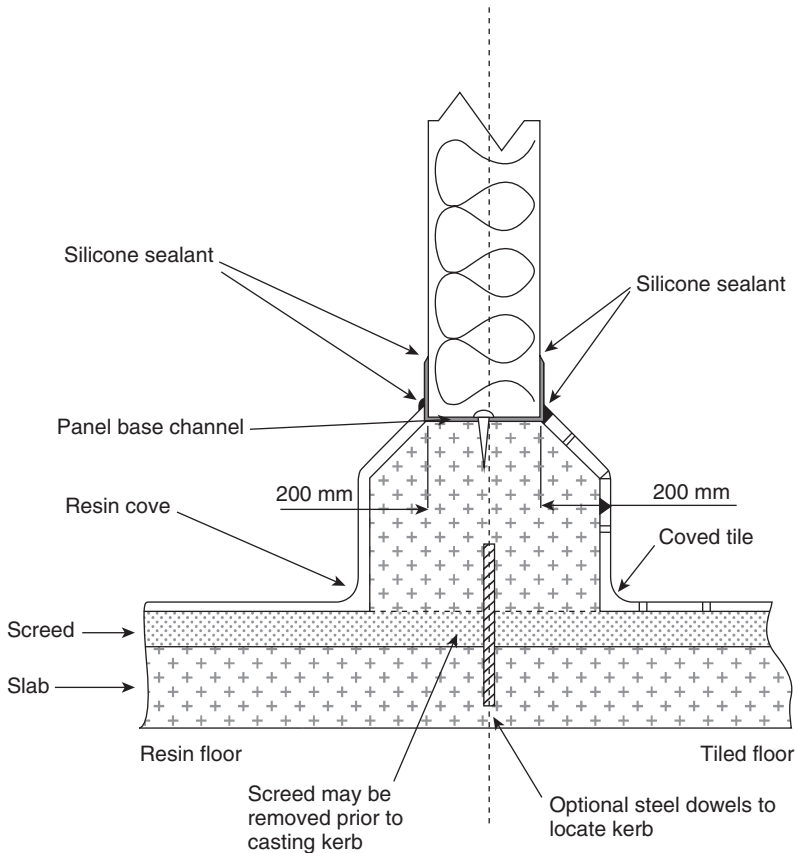
- light coloured;
- dense, tough, impact resisting, durable, rust proof and dust proof;
- impervious, non-adhesive to dust, non-absorbent, washable, water repellent and constructed of non-toxic materials;
- smooth and free from cracks and have any joints sealed with an impermeable sealant;

- unable to absorb grease or food particles or provide harbourage for pests;
- resistant to microbial (particularly mould) growth;
- able to withstand cleaning chemicals and methods used.

Liquid paint-based systems comprise a primer, one or more undercoats and one or more finishing coats. The finishing coats may be emulsion paints, oil-based, epoxy or polyurethane paints, or chlorinated or acrylated rubber paints. In areas where high levels of humidity or condensation occur regularly, it may be necessary to apply a fungicidal paint system to control the growth of moulds. Some paint systems rely on leaching of chemicals from within the paint to control mould growth. These types of paint are not generally considered suitable for use in food processing areas because of the potential contamination and taint hazard. Reinforced liquid coatings, based on glass fibres mixed with an epoxy resin, can also be used to provide a smooth finish which is easy to clean, and also gives good resistance to many chemicals, impact damage and abrasion, all of which are good hygienic features. However, taint problems can potentially arise during their application.

Modular insulated panels are now used very widely for non-load-bearing walls, particularly where thermal insulation is required. The panels are made of a core of insulating material between 50 and 200mm thick, sandwiched between steel sheets, which are bonded to both sides of the core. Careful consideration must be given, not only to the fire retardation of the wall insulation or coating material, but also to the toxicity of the fumes emitted in the event of a fire as these could hamper a fire-fighting operation. The steel cladding is generally slightly ribbed to provide greater rigidity and can be finished with a variety of hygienic surface coatings, ready for use. The modules are designed to lock together and allow a silicone sealant to provide a hygienic seal between the units. The modules can be mounted either directly (in a U-shaped channel) onto the floor or (preferably) on a concrete upstand or plinth (>150mm or 6in) or stainless steel channel filled with concrete (Fig. 3.7). The latter provides useful protection against the possibility of damage from vehicular traffic, particularly fork-lift trucks. However, it should be appreciated that this arrangement reduces the possibility of relatively easy and inexpensive changes to room layout to meet future production requirements. Sections fixed directly onto the floor must be properly bedded in silicone sealant and covered to provide an easily cleanable and watertight junction.

Movement joints must be designed to allow for expansion and/or contraction of the wall structure and must coincide with existing movement joints in the base slab. It is essential that provision is made for movement joints to be built in as work proceeds and not cut into finished work. Movement and expansion joints should be filled with a suitable packing and/or sealant material and the joint covered with metal angle or cover strip



**Fig. 3.7** Design and installation of internal walls and flooring.

to prevent rodent access to the joint. Fixing materials such as bolts and nuts, screws and nails should be smoothed away completely. If this is not possible, nut heads should fit smooth to the surface.

It is important that floor-to-wall, wall-to-wall and wall-to-ceiling joints are hygienically constructed. Covings should provide an easily cleaned surface at wall, floor and ceiling junctions. In floor-to-wall junctions, a 50 mm radius resin cove or a covered tile can be used, depending on the nature of the flooring material (tiles tend to be 30 mm in radius). Its upper joint is terminated by a galvanised or stainless steel stop bead secured to the wall, with the wall render finishing above this bead. Silicone sealant is used between the tile or resin and the stop bead to allow for thermal or other movement of the wall and flooring. Walls and other vulnerable structures such as doors and pillars should be protected by suitable barriers. Barriers may be wall or floor mounted and should be designed to prevent collisions

with the wall or other vulnerable structures by the specific types of transport systems, racking, wheeled bins, etc., used within the factory.

### 3.12 Doors

External doors shall be rodent proof (i.e. gaps < 6 mm) and ideally protected by an internal lobby with a self-closing door. If this is impracticable, then overlapping plastic strip curtains; rubber swing doors; or fans or air curtains which provide sufficient air velocity so as to prevent the entrance of insects; or an alternative approach shall be used. External doors should always be shut when not in use and if they have to be opened regularly, should be of a rapid opening and closing design.

Internal doors are to be easy to clean and, where necessary, to disinfect. Doors should be:

- light coloured;
- dense, tough, impact resisting, durable, rust proof and dust proof;
- impervious, non-absorbent, washable, water repellent, smooth, crevice free and constructed of non-hazardous materials;
- unable to absorb grease or food particles or provide harbourage for pests;
- able to withstand cleaning chemicals and methods used;
- suitably protected to prevent ingress of pests when opened;
- installed in close fitting frames that are fitted flush with the walls;
- protected from damage by moving equipment and traffic by, for example, guard rails or barriers;
- fitted with self-closers.

### 3.13 Windows

Food processing areas have traditionally been designed as far as possible without windows as glass is seen as a significant hazard to the food product. Recently, however, food management are questioning this approach as it can be argued that food operatives are more motivated when they can see their external environment. Where windows are present, the glass should be toughened and/or protected and inspected frequently for breakage as part of the company *Glass and hard plastics* policy. Where windows would result in contamination if opened, windows should remain closed and fixed during production. Windows that can be opened to the outside environment are to be fitted with insect-proof screens which can be easily removed for cleaning.

Windows should:

- be constructed to prevent the accumulation of dirt, light coloured and be easy to clean;

- be ideally double glazed or double windowed to prevent condensation;
- be of toughened glass (laminated) or plastic, protected against breakage;
- be installed at least 1.2m above floor level;
- be fitted with frames which are dense, tough, impact resisting, durable, rust proof, impervious, non-absorbent, washable, water repellent, smooth, crevice free and constructed of non-hazardous materials and able to withstand cleaning chemicals and methods used;
- have ledges (if fitted) sloped away from the glazing at 45°;
- be installed in close fitting frames which are fitted flush with, and continually sealed to, the walls.

Skylights should be clean, free from condensation and shall not open.

### 3.14 Ceilings

A ceiling must be provided in all processing areas. Ceilings (or where there are no ceilings the interior surface of the roof) and overhead fixtures (e.g. ducts, pipes, stairs and elevators) must be constructed and finished so as to prevent the accumulation of dirt and to reduce condensation and the shedding of particles. Ceilings should be:

- light coloured and cleanable;
- dense, tough, impact resisting, durable, rust proof and dust proof;
- impervious, non-absorbent, washable, water repellent and constructed of non-hazardous materials;
- smooth and free from cracks and have any joints sealed with an impermeable sealant;
- unable to absorb grease or food particles or provide harbourage for pests;
- resistant to microbial (particularly mould) growth;
- able to withstand cleaning chemicals and methods used;
- to a height of at least 3m to help prevent condensation.

False ceilings should be adequately supported and be sealed at their joints using a continuous flush seal. False ceilings should be provided with catwalks where necessary to facilitate cleaning and maintenance. Adequate access to the void shall be provided, which should be external to the processing area. Where there is no access to the space above the ceiling, the ceiling shall be totally sealed. False ceilings of a walk-on design are the preferred ceiling choice (Wessels, 2011), allowing services and lighting to be maintained from outside the food processing area. Lighting should be chosen that allows the bulbs to be changed from the false ceiling. It is important to ensure that drops from services passing through the ceiling are sealed properly to prevent ingress of contamination. Suspended ceilings, in which panels are held in a suspended metal grid, are not recommended for food processing areas.

### 3.15 Ventilation and temperature control

Food factories must have suitable and sufficient means of natural or mechanical ventilation to provide air flow for personnel that will not contaminate product. Where natural ventilation is appropriate, ventilation should be through openings (or openable sections) which are directly connected to the outside air and so positioned in the external walls and/or roof that effective cross-ventilation is possible: provided that such openings shall have a surface area equal to at least 5% of the floor area of the room concerned. Mechanical ventilation should be provided to:

- control odours which might affect the wholesomeness of food;
- control humidity (or condensation) – it is recommended that conditioned air has a relative humidity below 55% to restrict the growth of microorganisms, in particular moulds;
- control ambient temperatures to ensure the safety and suitability of foods;
- effectively remove particulates, fumes, smoke, steam and vapours;
- effectively remove excessive heat;
- reduce the number of airborne contaminants, including microorganisms.

The mechanical ventilation system should:

- comprise air handling units designed so as to allow easy access for inspection, maintenance and cleaning and which are positioned as far as possible, out of the processing area;
- have air filter systems designed and located so that dirty filter elements/mats are removed within an area of the lowest hygiene classification; a filtered air supply should be maintained to production areas at all times that production or cleaning is being undertaken – filters should be changed, therefore, out of production periods;
- have the minimum length of ductwork necessary to perform its adequate function;
- include air control facilities including temperature, humidity and filtration, appropriate to both the operations undertaken within the processing area and to the external environment;
- provide sufficient air changes per hour in enclosed processing and food handling areas (typically between 5 and 25 changes per hour);
- where necessary, have the capacity to totally dry the processing area at least once a day;
- provide airflows that are from clean areas (e.g. process areas) to dirty areas (e.g. raw material storage);
- comprise air supply and extraction trunking that does not introduce contaminants into products;
- have air intakes that are suitably screened against pest access, at least 1 m (3 feet) above internal and external ground levels and away from any other possible source of contamination, e.g. noxious solids,

vapours or gases or exhaust of materials that could contaminate other products;

- have intakes and extraction units positioned with due regard for the local environment and the avoidance of nuisance (odour, noise or dust emissions);
- if a filtered air supply is required to processing areas, a minimum level of filtration of >90% of 5 micron particles is required, e.g. G4 or F5 filters (BS EN 779, 2002), to provide both suitably clean air and prevent dust accumulation in the ductwork.

Where there is a risk of microbial contamination of the product by the surrounding air, the working area should be enclosed as far as possible and be maintained at a positive pressure using filtered air drawn from a clean source. The type of filters will depend on the product and process and range from dust exclusion filters to high-efficiency particulate air (HEPA) filters. Filtering should comply with minimally G5 but in some cases EU-class F7 or F8 (see filter standards) or an equivalent thereof. For high-risk areas air supply is critical and the following criteria apply:

- For high-risk applications, a series of filters is required to provide air to the desired standard and is usually made up of a G4/F5 panel or pocket pre-filter followed by an F9 rigid cell filter. For some high-risk operations an H10 or H11 final filter (85–85% retention of 0.5 micron particles) may be desirable, whilst for high-care operations an F7 or F8 final filter (80–95% retention of 1 micron particles) may be acceptable.
- The choice of filter is primarily driven by the length of time the food product is exposed to the air within high risk, as the vector of cross-contamination is via sedimentation of particles onto the food. If it is only a short time period (minutes) between the product exiting the decontamination treatment and filling into primary packaging, a lower level of filtration is required, whilst if the product is exposed for longer time periods (hours) higher filtration standards may be required (Curiel and Lelieveld, 2013).
- Higher levels of filtration are required for room air if the external microbial challenge is greater, e.g. if the factory is close to a sewage works, landfill site, abattoir, etc.
- A device should be installed to measure the pressure drop across the filters so that filters can be changed when their performance drops off due to clogging.
- The pressure differential between low and high risk should approach 5 Pa (>0.02 inch of water column). The desired pressure differential will be determined by both the number and size of openings and also the temperature differentials between low and high risk. If large temperature differentials exist, the velocity of air through the opening from high risk may need to be 1.5 m/s (5 ft/s) or greater to ensure that a one-way flow is maintained. Graham (2005) expresses the pressure differential as



0.01–0.02 inches of water column (2.5–5 Pa) or a flow rate of 250–350 feet/min (1.3–1.8 m/s) between rooms.

### 3.16 Lighting

All areas where food is examined processed or stored, and where equipment or utensils are cleaned, and in personnel changing areas, must have adequate natural and/or artificial lighting that provides sufficient light, on horizontal, vertical and inclined work surfaces, for the activities conducted. Where necessary, lighting should not be such that the resulting colour of the food product is misleading.

Natural lighting must be by means of unobstructed transparent surfaces in the external walls and/or roof which admit daylight, with an area equal to at least 10% of the floor area in the room concerned.

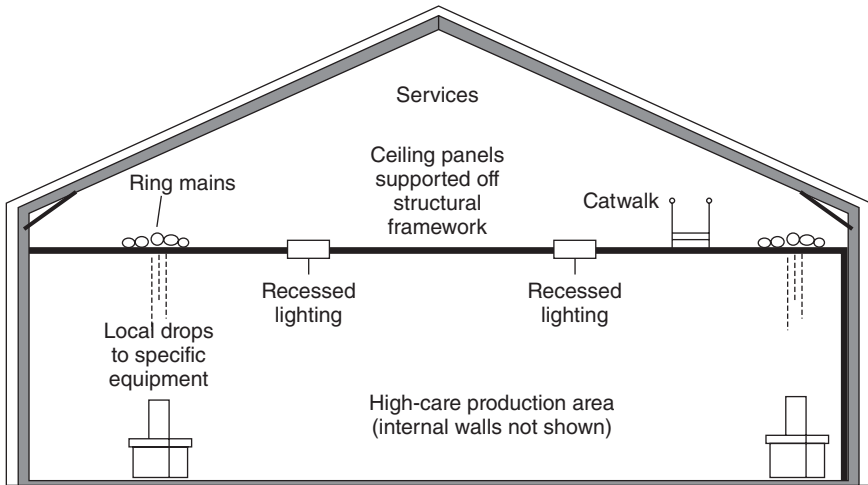
The lighting intensity should be adequate to the nature of the operation and should be not less than the following (Moerman, 2011):

- 550 lux in inspection areas;
- 440 lux in work areas;
- 110–220 lux in receiving and despatch areas, warehouses and storage rooms.

Lighting (and fire detection systems) should be suitably sealed to the ceiling or spaced off it to give easy access for inspection and cleaning with the top of the light fitting sloped to 45° to avoid accumulation of dirt and enable cleaning. Lighting fixtures should, where appropriate, (e.g. suspended over food or packaging materials) be protected to ensure that food or packaging is not contaminated by breakages. All light appliances should be protected by shatterproof plastic diffusers or sleeve covers or, where this is not possible, fine metal mesh screen. Lighting fixtures should be dismantlable so that the fixtures can be removed to a suitable area (e.g. engineering workshops) to facilitate safe bulb/tube replacement.

### 3.17 Services

Hygienic building design must take account of service equipment such as pipework for water, steam and compressed air; electrical conduits and trunking; artificial lighting units; ventilation ducts; compressors, refrigeration/heating units and pumps. Ashford (1986) suggests building a 'box within a box' by creating insulated clean rooms within the structural box of the factory, with the services and control equipment located in the roof void above the ceiling. Equipment and ductwork are suspended from the structural frames and access to all services is provided by catwalks, as shown in Fig. 3.8. This arrangement, if properly undertaken, eliminates a major source of contamination from the process area.



**Fig. 3.8** 'Box within a box' design of a factory interior to separate production from service operations.

Service pipes should be routed outside the process area and pass through walls local to their point of usage. Where this is not possible, services should be grouped 50mm apart on a stainless steel structure around the plant with minimum support rackets to walls or plant. Overhead pipes should not pass over open vessels or production lines. This is to prevent dripping of condensation droplets, which may form if the pipes are above a process area, and contamination from leakage, lagging, flaking paint or dust. Services should not be positioned too closely to walls and floors in production areas and should have a minimum 50mm clearance to allow for cleaning, inspection, maintenance and repair. Long runs of horizontal pipes must be avoided and pipework should be designed with suitable falls: dead legs, sharp bends, complex cross-piping and complicated valve systems should be avoided.

Cold water pipes and other service pipes which might be prone to condensation build-up should be insulated. The cladding used for pipework shall be suitable for use in a food area and be covered with aluminium, stainless steel or a suitable alternative.

All pipes and cables passing through internal walls and floors should be built in to prevent pests from using them as runways. Underground ductwork used for heating, water and other services can allow pests to move around within and between buildings. Barriers should be built across the duct at the outside wall of each building. Where ductwork carries pipes or cables from one part of a building to another they should be proofed at each floor level and access provided for inspection cleaning and treatment. The most effective way of passing services through walls is by means of sleeves or

prepared openings (Timperley, 2003). Ducts may pass through walls as follows:

- Cast directly into concrete wall or built into brickwork/blockwork. This is a costly and impractical solution because it requires separate supports to hold the duct in place and in the case of concrete makes it difficult to strip shutters.
- With flanges exposed on each side of the wall for connections. This method is prone to distortion and is difficult to cast into concrete walls.
- Running through an opening fixed with angles bolted to angle inserts in the wall. A seal is then made between the duct and the wall using a two-part polysulphide sealer, which provides a degree of flexure to accommodate thermal and other movement.
- Passing through the wall via a prepared opening using a concrete or steel lintel to bridge the gap. A seal is made between the duct and the wall using polysulphide.

Pipework services in processing areas may be stainless steel, galvanised steel or PVC. Steam should be transported in malleable iron pipes, which should be clad with stainless steel. Supports and hangers should be stainless steel or hot dip galvanised steel. Painted steel should be avoided to obviate the risk of paint flaking. Pipe insulation material must be CFC-free. Cladding must be crevice free with a durable surface.

The length of electrical cabling should be minimised, be situated behind walls, below the floor or above the ceiling. Vertical or inclined cable trays should be used with one layer of cables per tray. Alternatively, cables can be contained within stainless steel, aluminium or hard plastic conduits, though it is essential that these are sealed at both ends to prevent the ingress of soils, pests and microorganisms.

For dry food products, dust extraction equipment may need to be installed where considerable amounts of dust are generated and where dust is a hazard to product cross-contamination and to operative health and safety. The capture velocities of extractor fans and canopies must be sufficient to evacuate all dust, heat, fumes and other aerosols to the exterior as appropriate.

The design of the transport air and dust extraction systems should be of the same hygiene standards as for mechanical ventilation. Process or transport air should not be drawn from dry handling areas as these are usually potential areas of high dust loading and may need to be conditioned to prevent condensation as this may cause agglomeration and subsequent microbial growth.

Where necessary and dependent on the product and hazard analysis, further steps may be taken to filter air used in direct contact with the product (e.g. for product cooling or powder transport), by using a minimum of an EU Class F7 filter and up to a HEPA filter applied, at a point close to the line. Air used for the transport of product must be dust filtered as a

minimum and may require additional filtration, over and above that of the room air from the hygiene zone to which it is in or being moved to, to maintain product safety and quality. Higher levels of filtration than for room air are required for process air that is used to move dry products, as the interface between the air and the product is greatly in excess of simple sedimentation.

Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be dry and treated to be free of microorganisms, chemicals and particulates. Compressed air, carbon dioxide, nitrogen and oxygen shall be filtered through a micron filter (to remove particles of 0.5 microns or greater) located close to the point of use and should have non-return valves to preclude the entry of food. Compressed air should conform to the requirements of: *Food grade Compressed Air: A code of practice*. British Compressed Air Society Limited, [www.bcas.org.uk](http://www.bcas.org.uk).

Steam should be generated from potable water and should be adequate to meet operational requirements and should have traps to ensure adequate condensate removal and elimination of foreign materials (Stanley and Pedrosa, 2011). Steam should be filtered (to remove particles of 5 microns or greater) and should have non-return valves to prevent the draw-back of product into steam lines. Steam vents should be limited as much as possible, particularly in dry processing areas.

Mezzanine floors, stairs, catwalks, bridges, gangways and platforms, etc., over production lines shall be completely sealed and shall include side walls and walls around openings, at least 150 mm high, to preclude contamination of the area below. They should be constructed of rust-proofed, impervious, non-corrodible, easy-to-clean and impact-resistant materials and framework should be open rather than hollow section.

If elevators are to be used, separate elevators should be used for incoming and outgoing transport of goods, raw materials and end products. The floor of the elevator should not be of the 'double floor' type. Elevators should not connect zones of different hygiene classification and should not be used in high-risk areas.

### 3.18 Water

Food factories must have an adequate supply of potable (hot and cold) water, which is to be used whenever necessary to ensure that foodstuffs are not contaminated. Where appropriate, facilities for water storage, distribution and temperature control shall be adequately designed and constructed, shall be covered and shall have air vents that are insect and rodent proof. Storage tanks and reservoirs should be of an appropriate size, i.e. not so large as to present dead areas or lead to significant residence times. For example, in developed countries where interruptions to the

potable water supply are minimal, tanks designed to hold a factory supply for 24 hours may be appropriate.

Plumbing shall be of adequate size and design and adequately installed:

- to carry sufficient quantities of water to required locations throughout the plant;
- to ensure potable water is not contaminated with non-potable water;
- to prevent a source of contamination to food, water, equipment, utensils or create an unsanitary condition;
- to be able to be disinfected;
- so that all hoses, taps, and other similar sources of possible contamination prevent back-flow or back siphonage;
- to properly convey sewage and liquid disposal waste.

In dry processing factories, the infrastructure and equipment must be designed to accommodate water. The possibility of stagnant water should not occur, therefore any surface that can retain water (gutters, ledges or horizontal surfaces) should not be present inside the building. The installation of the water distribution systems should be considered carefully such that water pipes do not unnecessarily enter and run through dedicated dry areas.

Recirculated water should be treated, monitored and maintained as appropriate to the intended purpose. Recirculated water must have a separate distribution system that is clearly identified (e.g. by colour, marking or printed notices).

Where non-potable water is used, for example for fire control, refrigeration and other similar purposes, it is to circulate in a separate duly identified system. Non-potable water is not to connect with or allow reflux into, potable systems.

Local legislation must be followed with regard to protection of the potable water supply. A connection between the water supply piping and a make-up tank, such as for storage, cooling or condensing, should be protected by an air gap or effective backflow preventer. An air gap is the unobstructed vertical distance through the free atmosphere of at least twice the diameter of the largest incoming supply pipe to the flood level of the vessel or receptacle.

All water systems must be designed to prevent water stagnation. To limit the risk of *Legionella* growth within water systems, water supply tanks and calorifiers must be well enclosed, insulated and accessible with short, direct pipe work where the cold water pipes are lagged to prevent the water from warming to the critical range of 20–45 °C.

### 3.19 Food and solid waste

Adequate provision must be made for the storage and disposal of food waste, non-edible by products and other refuse, taking into account local

legislation requirements for waste categorisation. Waste storage areas must be designed and constructed so that the risk of contaminating food or the potable water supply is avoided and to minimise the potential for odour. Storage should be in a separate room or in an external area that is constructed of impervious material and suitably sloped and drained. Refuse stores are to be designed and managed in such a way as to enable them to be kept clean and suitably fly proofed and free from animals and pests.

Food waste, non-edible by-products and other refuse should be deposited in appropriately constructed, labelled, closable containers, made of impervious material, are leak-proof and are easy to clean and disinfect:

- Waste containers should be specifically identifiable (e.g. by colour) and be lidded.
- Waste containers should not be moved through different hygiene zones. Waste should be moved out of higher-risk zones via openings in the segregated barrier. For the disposal of small quantities of bagged waste in high-risk areas, existing hatches should be used, e.g. the wrapped product exit hatches or the packaging materials entrance hatch, as additional hatches increase the risk of external contamination and put extra demands on the air handling system. For waste collected in bins, it may be necessary to decant the waste through purpose built, easily cleanable from high risk, waste chutes that deposit directly into waste skips.

### 3.20 Conclusion

The hygienic demands on food factories, often led by product labelling, brand protection and food safety requirements, continues to grow and are leading to new design and refurbishment considerations. In terms of hazards, food factories must now prevent the ingress of microorganisms and pests, and then prevent their movement, harbourage and growth. Particulates and odours in the air must also be excluded. Within the factory, as well as the separate storage of dry, chilled, frozen, meat, dairy and vegetable ingredients, incompatible ingredients including allergens, organic ingredients, religious ingredients (halal, kosher), and GM ingredients must also be segregated. Finally, the building elements themselves must not give rise to chemical and physical hazards, particularly if they are food contact surfaces.

As well as controlling the sources of such hazards, the factory design must seek to prevent vectors that can move hazards to other food processing areas or directly to the food product. This requires effective design for the controlled movement of food ingredients, packaging and products, the movement of operatives, the movement of the air and the installation of equipment and services. This may also lead to the segregation of food processing operations for which cross-contamination may be difficult to

control, via separation into different buildings, in to different parts of buildings or via segregated processing times, in which food manufacturing processes using ingredients that may be hazardous to other products are processed last prior to effective cleaning and disinfection systems.

Hygienic factory design thus contributes to the manufacture of safe and wholesome food products whilst helping to ensure that ‘vegetarian’, ‘organic’, ‘halal’, ‘kosher’ and ‘GMO free’ product label claims are effectively supported.

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## 4

# Hygienic design of food processing equipment

**H. L. M. Lelieveld, formerly Unilever R&D, The Netherlands and  
M. A. Mostert and G. J. Curiel, Unilever R&D Vlaardingen,  
The Netherlands**

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**Abstract:** Improperly designed processing equipment may affect the microbiological and chemical safety of the product and even result in physical contamination. It is therefore essential that all equipment that comes into contact with the product is of hygienic design, which in many countries is also a regulatory requirement. This chapter explains the principles of such design and how to meet them and discusses potential pitfalls. Examples are given of correct and wrong designs of equipment for both closed and open processing.

**Key words:** hygienic equipment design, design criteria, cleanability, food contact surfaces, food safety.

## 4.1 Introduction: key criteria in hygienic design

The purpose of hygienic equipment design is to (Shapton and Shapton, 1991):

- give maximum protection to the product;
- provide product contact surfaces necessary for processing that will not contaminate the product and are readily cleanable;
- provide junctures which minimise ‘dead’ areas where chemical or microbial contamination may occur;
- give access for cleaning, maintenance and inspection.

Food contact areas include all surfaces that are directly exposed to the product and all indirect surfaces from which splashed product, condensate, liquid or dust may drain, drop or be drawn into the product (Shapton and Shapton, 1991). This means that, in the hygienic design of equipment for open processing, the area above the product processing surface must also be taken into consideration.

### 4.1.1 Safety

Good hygienic design prevents the contamination of the product with substances that would adversely affect the health of the consumer (Holah, 2002). Such contamination might be microbial (e.g. pathogens), chemical (e.g. lubricating fluids, cleaning chemicals) or physical (e.g. glass). There have been many examples of product recalls, lost production and even site closure due to contamination arising from poorly designed equipment. A recent example is the design of food trays that were used to transport salmon on a conveyor belt. The sides of the trays (made from polyvinylchloride (PVC), polytetrafluoroethylene (PTFE)) were porous (Jan Foppen, cited by Postma, 2012). That this is dangerous has been known for a long time and has been discussed (e.g. on page 151 in the first edition of this book – Lelieveld, *et al.*, 2003).

Physical foreign body contaminants, such as pieces of plastic, affect the wholesomeness of food but rarely receive media attention. Physical contaminants of a more serious nature, e.g. glass fragments or caustic cleaning-in-place (CIP) fluids, however, are much more serious. Perhaps of most concern are pathogenic microorganisms such as *Listeria* or *Escherichia coli* O157:H7, which may be harboured in equipment and then subsequently grow during production and contaminate the product. Under favourable conditions such microorganisms grow very rapidly. Consequently gaps and crevices, where microorganisms can harbour and multiply, must be avoided (Lelieveld, 2000). Good hygienic design also maintains product in the main product flow. This ensures that product is not 'held-up' within the equipment where it could deteriorate, affect product quality on rejoining the main product flow, and encourage the growth of spoilage and pathogenic bacteria (Wirtanen, 1995).

### 4.1.2 Cleaning

Cleanliness is clearly essential in preventing contamination. If product residues accumulate, microorganisms can multiply rapidly. Equipment that is difficult to clean will also need more frequent cleaning, more aggressive chemicals and longer cleaning and decontamination cycles (Hauser *et al.*, 1989; Timmerman, Chapter 17). The result will be higher cost, reduced availability for production, reduced lifetime of the equipment, and more effluent. To be cleaned effectively, surfaces must be smooth and free from crevices, sharp corners, protrusions and 'shadow' zones, not only when new but during the lifetime of the equipment (Holah, 2000; Timperley and Timperley, 1993).

### 4.1.3 Inspection

Irrespective of the quality of hygienic design, experience has shown that inspection, testing and validation of the resulting design are very important

in checking whether hygienic requirements have been met (Holah, 2002). In some cases it may be necessary to check cleanliness as part of maintenance procedures. The equipment designer has to make sure that relevant areas are accessible for inspection and/or validation (Venema-Keur *et al.*, 1997).

#### **4.1.4 Compatibility with processing function**

A design with excellent hygienic characteristics but unable to perform its functional duties is of no use, and a designer may have to compromise (Lelieveld, 2000). Any compromise between hygienic design and processing function will, however, have to be compensated by more intensive and possibly also more frequent cleaning and decontamination procedures. This must be well documented so that users of the equipment are aware of the nature of the compromise. Where an acceptable compromise cannot be reached, hygienic requirements must prevail even if this reduces the potential processing efficiency of the equipment. However, good hygienic design reduces the time required for a piece of equipment to be cleaned. This reduction of cleaning time is significant over the lifetime of the equipment. Hygienically designed equipment that is initially more expensive (compared to similarly performing poorly designed equipment) will be more cost-effective in the long term. In addition, savings in cleaning time may lead to increased production. Upgrading existing designs to meet hygienic requirements can be prohibitively expensive and may be unsuccessful. Ideally hygienic requirements should be taken into account at the design stage. Complying with hygienic requirements may increase the life expectancy of equipment, reduce maintenance and consequently lead to lower manufacturing costs (Timmerman, Chapter 17).

## **4.2 Risk assessment in equipment design**

Food processing equipment is designed and built to be suitable for a purpose. In practice, this means different levels of hygienic design for differing pieces of equipment (Holah, 2000). As an example, a mixer for *raw* meat need not be designed to the same hygienic level as a slicer of cooked meats (Timperley and Timperley, 1993). Similarly, aseptic fillers have usually been designed to a much higher hygiene standard than filling machines (VDMA, 2007). This difference in standards of hygienic design is related to the risk of a hazard being transferred from the equipment to the product produced and thus the consumer (Lelieveld, 1994).

The degree of risk from eating foodstuffs is dependent to a large extent on how that product has been processed, its degree of preservation and what further cooking steps (if any) the consumer has to perform prior to consumption. As an example, a stable preserved product, e.g. canned or dried goods, or one that requires thorough cooking prior to consumption,

is less likely to confer a microbiological risk than a ready-to-eat chilled food (Brown, 2002). All of the above food products may, however, convey similar risks in terms of non-microbiological hazards, i.e. physical hazards (e.g. glass, plastic), chemical hazards (e.g. lubricating fluids, cleaning chemicals, pesticides) or allergens (e.g. milk, soy, eggs, nuts). In deciding hygienic requirements, the designer and manufacturer of food processing equipment need to:

- identify the process for which the machine is intended;
- identify the relevant hazards associated with the products produced;
- design methods/measures which can eliminate hazards or reduce their risk;
- identify any other hazards introduced by the methods used to reduce the hazard under analysis;
- verify the effectiveness of the hazard elimination or risk reduction;
- describe any residual risks and any additional precautions necessary for the machine's safe use.

To help equipment manufacturers meet this challenge, and thus both control the risk of transfer of a hazard to a food product during manufacture and produce the equipment in a cost-effective manner, food manufacturers should enter a dialogue with equipment manufacturers to consider the following:

- **The intended use of the equipment.** Will the equipment be used for one specific purpose only, for which the hazards are readily identifiable, or could the machine be used for a wide range of products in many industries (e.g. a pump)?
- **The product type to be processed.** Will the product be already contaminated (e.g. a raw material) or will it be 'preserved' or 'aseptic'?
- **The degree of further product processing.** Will the product processed by the equipment subsequently undergo a further process, which functions as a hazard elimination step (e.g. a heat treatment) or is the process for which the machine is intended the final process?
- **The degree of cleaning and/or inspection.** Is the equipment to be cleaned and/or inspected after every use, routinely during the day, every day or every week, for example?
- **The use of the machine.** Is the equipment likely to be well maintained, is it used infrequently? Is it designed for intensive or continuous use? Is it susceptible to abuse?

After a risk assessment has been made, it is possible to assign the suitability of an item of equipment to one of several categories for intended use (Holah, 2000). These can be described as follows:

- Equipment that satisfies the minimum requirements to make it safe for its intended purpose. This may involve the control of single hazards, e.g. the equipment contains no glass.

- Equipment that satisfies all the current best-practice hygienic design criteria and is thus fit for the production of most foods, though it needs to be dismantled prior to cleaning.
- Equipment that satisfies all the current best-practice hygienic design criteria and can be cleaned without dismantling.
- Equipment that satisfies all the current best-practice hygienic design criteria and is designed for a specific heat or chemical decontamination treatment.
- Equipment that satisfies all the current best-practice hygienic design criteria, is also designed for a specific heat or chemical decontamination treatment and will prevent ingress of microorganisms. Such equipment would be suitable, for example, for the production of aseptic foods.

Whilst it is acceptable (though not necessarily cost-effective) to use equipment designed for a higher hygienic requirement for a lower-risk product, it is unlikely to be acceptable to use equipment designed for a lower-risk category or food products for higher risk or aseptic products.

### **4.3 Regulatory requirements for hygienic equipment design: the European Union (EU)**

In the EU, the Council Directive *on the approximation of the laws of Member States relating to machinery* (89/392/EEC) was first published on 14 June 1989 and recast in 2006. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (replacing the Directive 98/37/EC (14 June 1989 89/392/EEC) and amendments) The Directive includes a section dealing with hygiene and design requirements which states that machinery intended for the preparation and processing of foodstuffs, cosmetics or pharmaceutical products must be designed and constructed so as to avoid health risks. It consists of seven hygiene rules that must be observed. These are concerned with the following:

- materials in contact with food;
- surface smoothness;
- preference for welding or continuous bonding rather than fastenings;
- design for cleanability and disinfection;
- good surface drainage;
- prevention of dead spaces which cannot be cleaned;
- design to prevent product contamination by ancillary substances, e.g. lubricants.

The Directive requires that all machinery sold within the EU shall meet these basic standards and be marked accordingly to show compliance (the 'CE' mark).

Subsequent to this Directive, a European Standard EN 1672-2:2005+A1:2009, *Food processing machinery – Safety and hygiene requirements – Basic concepts – Part 2: Hygiene requirements* (Anon., 2009), has been adopted to further clarify the hygiene rules established in 2006/42/EC. In addition to this, a number of specific standards on bakery, meat, catering, edible oils, vending and dispensing, pasta, bulk milk coolers, cereal processing and dairy equipment have been produced (Holah, 2000). This is an ongoing process and readers are directed to their national standards office for an update on food process equipment safety and hygiene standards (e.g. for standards in English, please see <http://www.bsigroup.co.uk/>).

The hygiene requirements presented in EN 1672-2:2005+A1 are as follows:

- Hygiene risk assessment.
- Materials of construction. Materials used for product contact must have adequate strength over a wide temperature range, a reasonable life, be non-tainting, corrosion and abrasion resistant, easily cleaned and capable of being shaped. Stainless steel usually meets all these requirements. There are various grades of stainless steel. They must be chosen for their particular properties to meet differing operational requirements, e.g. Type 316 that contains molybdenum and is used where improved corrosion resistance is necessary (Chapter 5).

- Design

The basic hygienic design requirements for the food area can be summarised under 10 sub-headings and are described below:

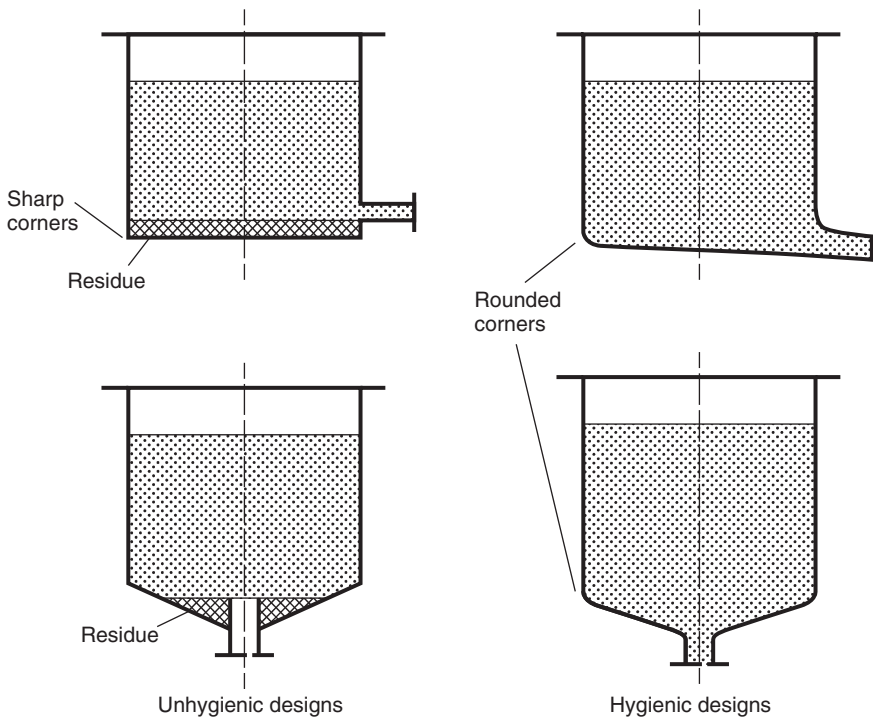
1. **Surface finish.** Product contact surfaces must be finished to a degree of surface roughness that is smooth enough to enable them to be easily cleaned. Rougher surfaces will deteriorate more rapidly with age and wear (abrasion), making cleaning more difficult.
2. **Joints.** Permanent joints, such as those that are welded, should be smooth and continuous. Dismountable joints, such as screwed pipe couplings, must be crevice-free and provide a smooth continuous surface on the product side. Flanged joints must be sealed with a gasket because, although metal/metal joints can be made seemingly leak-tight, they may still permit the ingress of microorganisms.
3. **Fasteners.** Exposed screw threads, nuts, bolts, screws and rivets must be avoided wherever possible in product contact areas. Alternative methods of fastening can be used where the washer used has a rubber compressible insert to form a cleanable and bacteria-tight seal.
4. **Drainage.** All pipelines and equipment surfaces should be self-draining because residual liquids can lead to microbial growth or, in the case of cleaning fluids, result in contamination of product.
5. **Internal angles and corners.** These should be well radiused, wherever possible, to facilitate cleaning.

6. **Dead spaces.** As well as ensuring that there are no dead spaces in the design of equipment, care must be taken that they are not introduced during installation.
7. **Bearings and shaft seals.** Bearings should, wherever possible, be mounted outside the product area to avoid possible contamination of product by lubricants (unless these are edible), or to avoid possible failure of the bearings due to the ingress of the product. Shaft seals must be designed to be easily cleaned. If they are not lubricated by the product itself, then the lubricant used must be edible. Where a bearing is within the product area, such as a foot bearing for an agitator shaft in a vessel, it is important that there is a groove completely through the bore of the bush, from top to bottom to permit the passage of cleaning fluid.
8. **Instrumentation.** Instruments must be constructed from appropriate materials. If they contain a transmitting fluid, such as in a bourdon tube pressure gauge, the fluid must be approved for food contact. Many instruments themselves are hygienic but often they are installed unhygienically.
9. **Doors, covers and panels.** Doors, covers and panels should be designed so that they prevent the entry of and/or prevent the accumulation of soil. Where appropriate they should be sloped to an outside edge and should be easily removed to facilitate cleaning.
10. **Controls.** These should be designed to prevent the ingress of contamination and should be easily cleanable, particularly those that are repeatedly touched by food handlers to allow process operation.

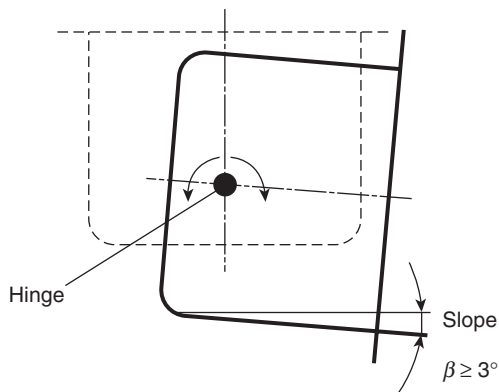
#### 4.4 Drainability

All pipelines and equipment surfaces should be self-draining, because residual liquids can lead to microbial growth or, in the case of cleaning fluids, result in contamination of product (Anon., 1983). Care should be undertaken with the installation of equipment so that its drainability is not impaired. Sharp corners must be avoided to ensure good drainability and cleanability. Corners must also be properly radiused. Surfaces and pipes should not be completely horizontal but slope towards drain points and there should be no ridges that may hamper draining (Anon., 1980). Horizontal surfaces must have a slope of more than 3° towards the outlet. In the case of external surfaces, sloping should result in any liquid flowing away from the main product area (Hauser *et al.*, 2004b).

Food-containing equipment (tanks, containers, vessels, troughs, reservoirs, hoppers, bins, chutes) with discharge openings must also be fully self-drainable. Figure 4.1 illustrates at the left two examples of non-drainable designs with discharge outlet above the lowest level and at the right two examples of self-drainable designs with discharge openings at the lowest



**Fig. 4.1** Self-draining container designs.

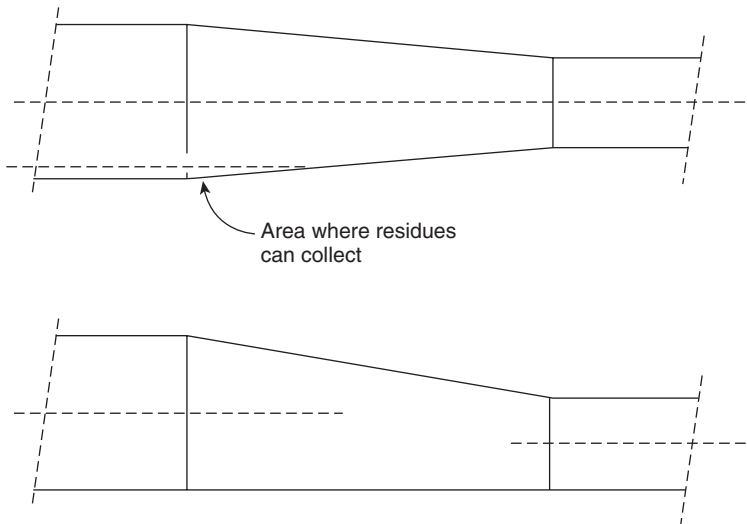


**Fig. 4.2** Hygienic design of tipping containers.

level, sloped bottoms ( $\geq 3^\circ$ ) and well-rounded corners. Equipment that can be tipped for discharging must also have well-rounded corners and be fully drainable and easily cleanable (Fig. 4.2).

Care must be taken that any closed process line can be fully drained. Piping should slope  $3^\circ$  towards draining points. Even smooth constructions





**Fig. 4.3** Hygienic connection of pipes of different diameters: the upper design hampers draining; the lower design facilitates draining.

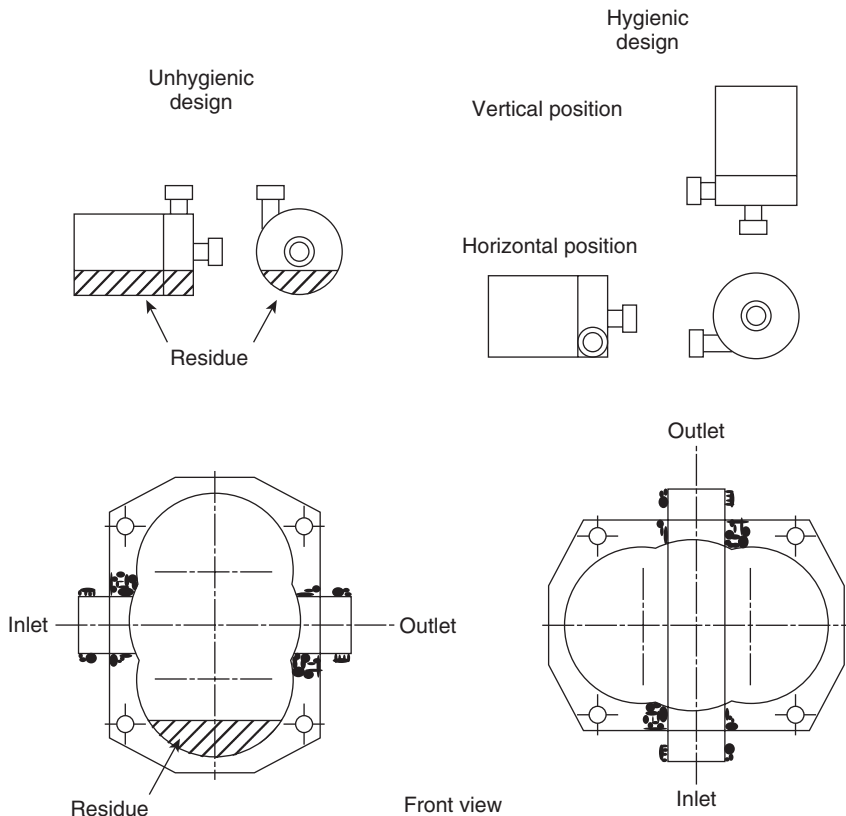
may hamper draining. This is illustrated in Fig. 4.3, which shows the connection between pipes of different diameters (Hauser *et al.*, 2007). Although for vertical piping a concentric reducer is fully acceptable, this is not so for horizontal piping, where it would affect drainability. For horizontal piping an eccentric reducer must be used. Self-evidently, reducers should be long enough to avoid shadow zones. Some types of pumps are traditionally positioned in such a way that draining is impossible without dismantling. The same type of pumps can also be designed for positioning in a drainable position (Fig. 4.4).

Where it is not possible to build equipment in such a way that proper draining is possible, procedures must be designed to ensure that residues of cleaning and disinfection liquids can be removed in another way. The method used should be well documented with clear instructions.

## 4.5 Materials of construction

Materials used for product contact must:

- have adequate strength over a wide temperature range;
- be durable and have a reasonable life;
- be non-toxic, non-tainting and non-absorbent;
- be resistant to cracking, chipping, flaking corrosion and abrasion;
- prevent penetration of unwanted matter under intended use;
- be easily cleaned and capable of being shaped (Hauser *et al.*, 2004a).



**Fig. 4.4** Hygienic and unhygienic design of centrifugal (top) and lobe (bottom) pumps.

Stainless steel usually meets all these requirements. There are various grades of stainless steel, which can be selected for their particular properties to meet operational requirements, for example Type 316 which contains molybdenum and can be used where improved corrosion resistance is necessary. It is important to avoid direct metal-to-metal joints other than by welding since metal-to-metal contact may harbour soil and microorganisms. In the case of equipment intended for aseptic processing, metal-to-metal seals will not prevent the ingress of bacteria. Elastomers and other polymers should retain their surface and conformational characteristics when exposed to the conditions encountered in production, cleaning and decontamination.

Materials for non-food-contact surfaces must be easily cleanable and resistant to the product and to cleaning and disinfecting agents. As with product contact surfaces, stainless steel is to be preferred. If components

are coated (e.g. motors, drives, casings) the coating must be non-toxic and resistant to cracking, chipping or flaking. Coated components should not be positioned directly above open product areas. Insulation must be vapour tight to avoid growth of microorganisms. Materials of construction are dealt with in detail in Chapter 5.

## 4.6 Surface finish

All surfaces in contact with foodstuffs must be easily cleanable (Holah and Thorpe, 1990). Surfaces must therefore be smooth, continuous and free from cracks, crevices, scratches and pits that may harbour and retain soil and/or microorganisms after cleaning. Although good cleanability is the key requirement for surfaces rather than smoothness, a maximum roughness is specified for food contact surfaces since cleaning time required increases with surface roughness. Both the American 3-A organisation and the European Hygienic Equipment Design Group (EHEDG) specify a maximum roughness for food contact surfaces (3-A Sanitary Standards Committee, 1995; Hauser *et al.*, 2004a). Product contact surfaces should have a finish of an acceptable  $R_a$  value and be free of imperfections such as pits, folds and crevices (for definition of  $R_a$ , see ISO standard no. 468, ISO, 1982). For large surface areas product contact surfaces should have a surface finish of  $0.8\mu\text{m } R_a$  or better (Hauser *et al.*, 2004a). A roughness of  $>0.8\mu\text{m}$  may be acceptable if test results have shown that the required cleanability is achieved because of other design features. For closed equipment (that is used for liquid handling and usually is CIP) a surface finish of  $0.8\mu\text{m } R_a$  is recommended, with higher  $R_a$  values being acceptable if they can be shown to be cleanable. It should be noted that cold rolled steel in most cases has a roughness of  $R_a$  0.2–0.5  $\mu\text{m}$  and therefore usually does not need to be polished to meet surface roughness requirements, provided the product contact surfaces are free from pits, folds and crevices when in the final fabricated form. However, grinding is required for hot-rolled steel unless there are special requirements regarding the process involved. As the surface roughness of cast materials and carbon steels does not meet the recommended figure, the cleanability of the components made with these materials will require further investigation. Non-product contact surfaces must also be smooth enough to ensure that cleaning is easy. Porous surfaces are usually unacceptable.

Table 4.1 shows the surface roughness achieved by differing surface treatments of stainless steel. It is important to measure whether the intended surface roughness has been achieved. Measuring instruments are readily available and, for surfaces that cannot be reached by such an instrument, surface replicas can be made for indirect measurement.

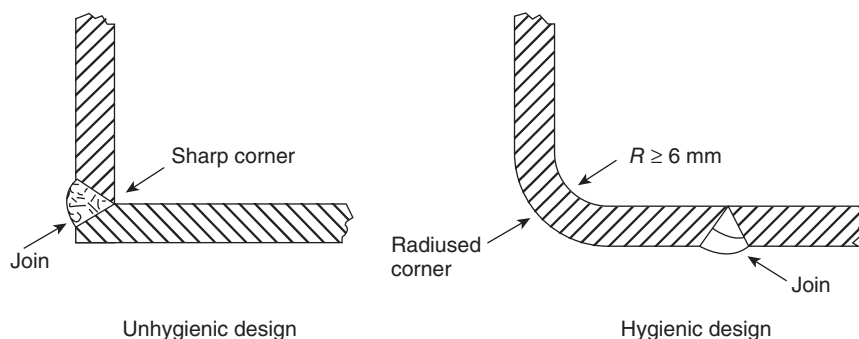
**Table 4.1** Examples of surface treatments of stainless steel and resulting surface roughnesses

Treatment	$R_a$ in $\mu\text{m}$
Cold-rolled stainless steel	0.2–0.5
Hot-rolled stainless steel	>4
Glass bead blasting (depending on bead size)	
1.0–1.2 descaling	
0.6–1.3	
Bright-annealing	0.4–1.2
Pickling	0.5–1.0
Electropolishing	Electropolishing does little to improve $R_a$ value, but does round off peaks, improving cleanability
Mechanical polishing with aluminium oxide or silicon carbide, abrasive grit number:	
500	0.1–0.25
320	0.15–0.4
240	0.2–0.5
180	$\leq 0.6$
120	$\leq 1.1$
60	$\leq 3.5$

## 4.7 Corners, crevices and dead spaces

Corners should be well rounded or radiused, wherever possible, to facilitate cleaning (Anon., 1983). Corners should preferably have a radius equal to or larger than 6 mm with a minimum radius of 3 mm. Sharp corners ( $<90^\circ$ ) must be avoided. Possible exceptions are equipment where the sharp corner is continually swept, such as lobe pumps. If sharp corners cannot be avoided or, for technical reasons, the radius of a corner must be smaller than 3 mm, the design must be such that the loss of cleanability is compensated. If used as a sealing point, corners (larger than  $180^\circ$ ) must be sharp to form a tight seal at the point closest to the product/gasket interface. Edges must be deburred. Figure 4.5 shows a weld creating a sharp corner and a radiused corner with weld away from it.

Crevices should be avoided since they cannot be cleaned. They retain product residues that effectively protect microorganisms against inactivation. In most cases, crevices are the result of poor equipment design. When parts of equipment must be mounted together, metal-to-metal contacts (other than welds) must be avoided as they leave very narrow and deep crevices. Elastomers should be used between metal components. The elastomeric material must be mounted in such a way that the seal is at the product side and that, to prevent destruction of the elastomer, excessive compression is prevented. This can be achieved by including design features

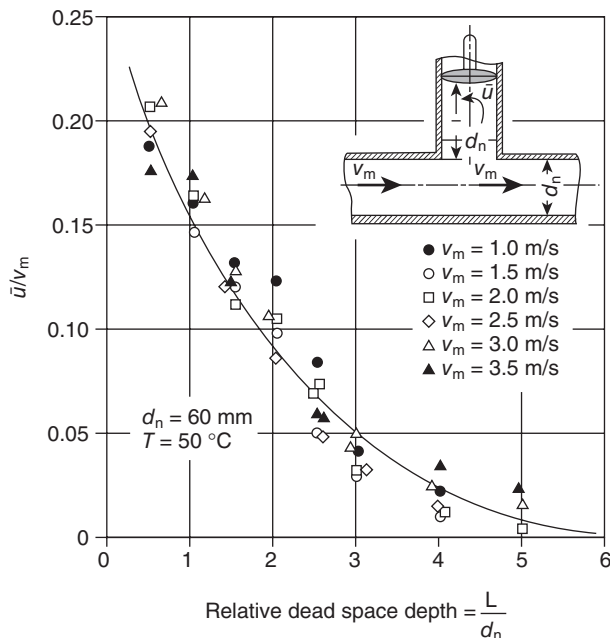


**Fig. 4.5** Hygienic and unhygienic welding: corners.

that align the surfaces of the various parts and provide a metal stop (Hauser *et al.*, 2004b, 2007). Care must be taken in the use of o-rings since these can also create crevices (Baumbach *et al.*, 1997). Seals are discussed in more detail later in this chapter.

In some cases crevices are unavoidable. This may be the case if slide bearings are needed in contact with product (e.g. as bottom bearings or top-driven stirrers and as bearings in scraped surface heat exchangers). Their presence should be taken into account when writing procedures for cleaning and disinfection. These procedures may need instruction for partial or total dismantling of equipment for cleaning and specific procedures for cleaning and reassembling component parts.

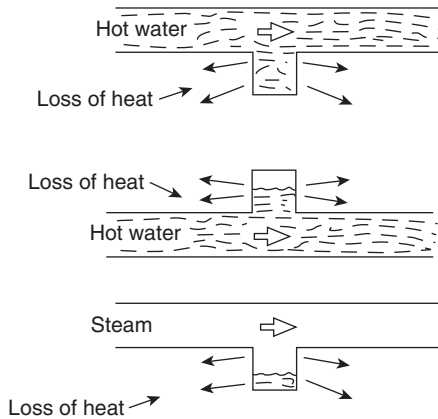
Dead spaces and shadow zones are areas outside the main product flow (Hauser *et al.*, 2007). Typical examples are T-sections in pipes used, for example, to mount sensors such as pressure gauges. Figure 4.6 shows the decrease in product flow velocity relative to the depth of the T-section. In this example, where the length of the T-section is equivalent to the diameter of the main pipe, a flow velocity of 2 m/s in the main pipe results in a velocity of 0.3 m/s in the T-section. This decrease in flow velocity provides a relatively stable pocket or 'dead leg' in which product residues can accumulate and microorganisms begin to multiply. During cleaning there is much less transfer of energy to the food residues (soil) in zones that are outside the main flow of cleaning liquids than to the soil in the main flow. Such areas are difficult to clean and therefore should be avoided. Effective cleaning requires a velocity of cleaning liquid of 1.5 m/s (Timperley, 1981). Lower velocities may dramatically increase the time required for cleaning. If hot water is used to pasteurise a process line, an upward pointing leg of a T-section will trap air, thereby reducing the rate of heat transfer and causing the decontamination of the dead leg – and what is connected to it – to fail. If a process line is sterilised with steam, an upward pointing dead leg, if clean and not too long, will probably be decontaminated properly, as steam will condense on the surfaces of the leg and fall down to let more steam



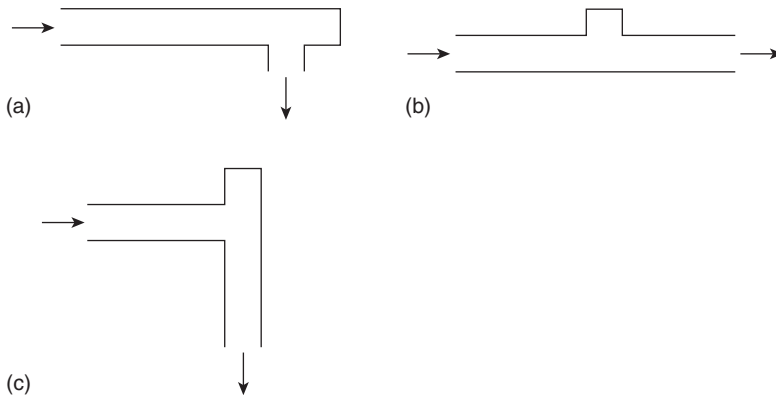
**Fig. 4.6** Fluid motion in a dead space: decrease in product flow velocity relative to the depth of a T-section.

condense and give off its energy. With steam sterilisation, downward pointing legs present problems. Here condensation will be collected in the leg and hamper heat transfer. The temperature will be too low for complete sterilisation (unless the presence of the leg has been taken into account in defining sterilisation procedures). A downward pointing T-section may also compromise sterilisation by hot water since the temperatures of the surfaces in the dead area, which will be outside the main flow of hot water, may be too low. The impact of T-sections on decontamination is shown in Fig. 4.7. If a downwards-pointing dead leg is present and the line is decontaminated with hot water, the heat transfer to the surface of that dead leg may be insufficient for the heat treatment required. If an upwards pointing dead leg is present and the line is treated with hot water, air trapped in the dead leg will prevent contact of a part of the surface with water and hence that part will not reach the correct temperature for the desired time. In the case that a line is sterilised with steam, a downwards-pointing dead leg will collect condensate and be at a lower temperature than the steam above.

A properly designed food processing line therefore should not have unnecessary dead legs. Those that are unavoidable should be in the correct position for the selected decontamination treatment. If unavoidable, their presence should be taken into account when devising cleaning and



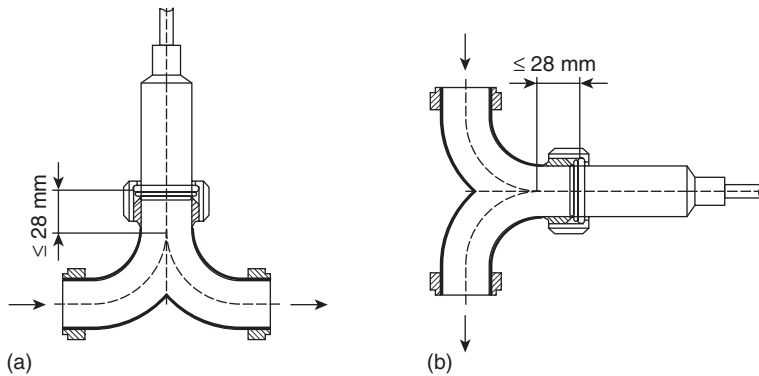
**Fig. 4.7** Adverse effect of dead legs in pipe lines on heat treatments with water or steam. The dead legs will be at a lower temperature than intended.



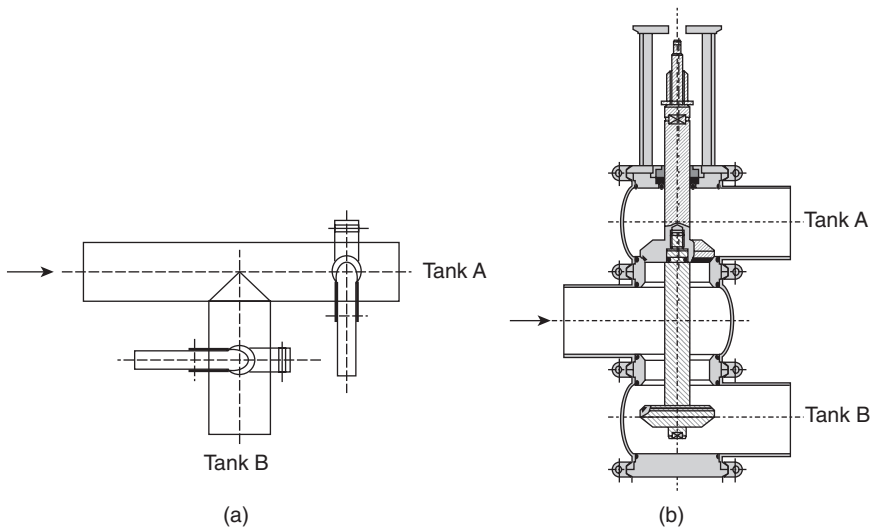
**Fig. 4.8** Optimal positioning of dead legs.

disinfection procedures. Duration and temperature of treatment must be clearly described in operation procedures (Hauser *et al.*, 2007).

If a T-section is unavoidable, it must be as short as possible (Anon., 1973). For pipe diameters of 25 mm it should have a depth of preferably less than 28 mm. For smaller pipe diameters the length should be smaller than the diameter, because otherwise cleaning becomes extremely difficult. For most liquids, the dead leg should be positioned as shown in Fig. 4.8(a). This configuration may not be suitable, however, if products contain any particulate matter, likely to accumulate in the dead leg. Configurations (b) and (c) may be acceptable only if the dead leg is very short. In all cases, the cleaning procedure must take the presence of the dead leg into account. The direction of the flow of product has a significant influence on the residence time in the dead leg and therefore should be as indicated. If



**Fig. 4.9** Optimal depth of T-sections relative to pipe diameter.

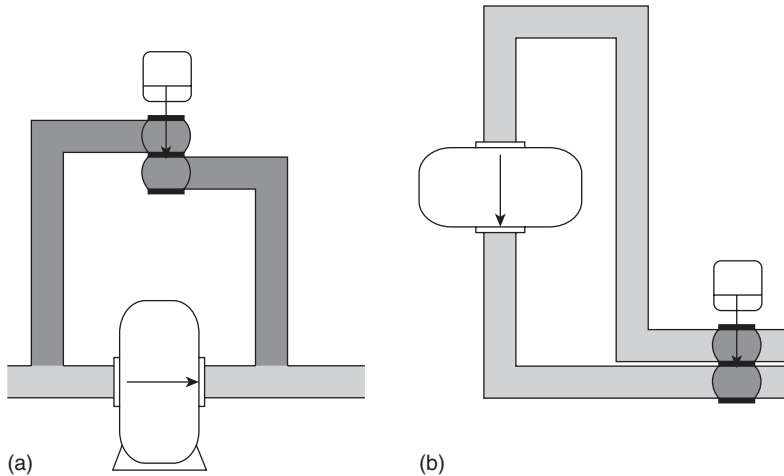


**Fig. 4.10** Unhygienic (a) and hygienic (b) product flow diversion.

T-sections are necessary, short right-angle tees or so-called swept tees (Fig. 4.9) may be used. Swept tees must be used with caution, however, as in horizontal pipelines, as shown in Fig. 4.9(a), a swept tee could hamper draining. Swept tees are best mounted in a vertical pipeline, as in Fig. 4.9(b).

Flow diversion should not be done in a way that would cause part of the product to stand still in a dead leg (Fig. 4.10). The two-valve system for flow diversion (Fig. 4.10(a)) creates a dead leg towards the closed valve. The correct type of valve is shown in Fig. 4.10(b). Dead areas are also created where product pumps are equipped with a pressure relief valve or with a bypass in case the pumps have insufficient capacity for circulating the cleaning liquid at the required velocity (Fig. 4.11). During production in



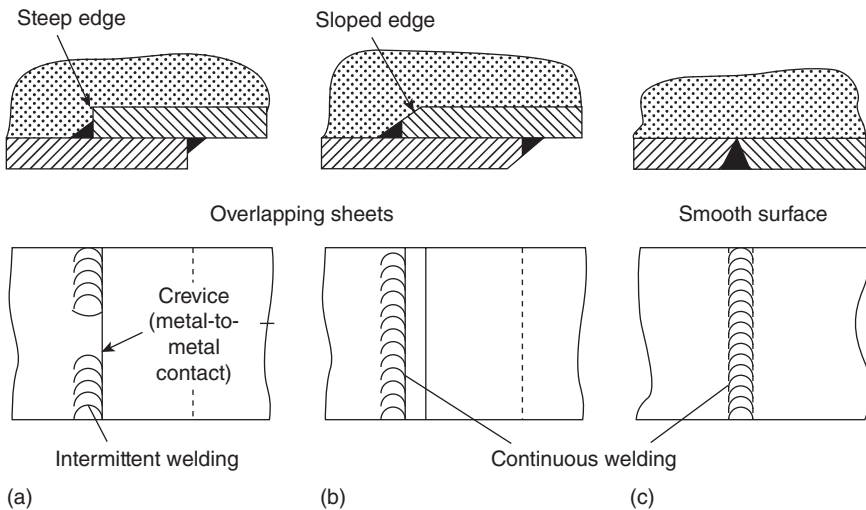


**Fig. 4.11** Unhygienic (a) and hygienic (b) position of a lobe pump and bypass.

configuration (a) product is entrapped in two large-volume dead legs when the valve is closed. Such product may spoil and infect the passing product. In open position, the valve provides a bypass to relieve pressure or to allow a higher flow rate of cleaning fluid through the process line than the pump would allow. Note that in such cases the pump and the piping between pump and valve may need a longer time for cleaning. The pump on the left is also shown in a position that does not allow draining. With the same valve it is also possible to construct a dead leg-free bypass as in Fig. 4.11(b).

## 4.8 Welds and joints

Joints should be avoided where possible. Bending of pipes is preferable to the use of prefabricated bends with couplings. If pipe bending is not possible, welding is preferred, provided that the welding is done correctly to ensure a smooth and continuous weld (Barnickel *et al.*, 2006). It is better to use permanent joints rather than dismountable joints to reduce the hygienic risks caused by projections, protrusions, edges, recesses, metal-to-metal contact and crevices in sealing gaskets (Hauser *et al.*, 2004b). Permanent joints, such as those that are welded or bonded, should be smooth and continuous and free from recesses, gaps or crevices. They should preferably be welded. There are several types of common defects arising in welded joints (e.g. misalignment, cracking, porosity, inclusions), which can act as a source of microbiological problems. To avoid these problems, the product contact surface of welds must be smooth (ground flush with the surrounding surface). To avoid crevices through metal-to-metal contact, the welded seams must not be intermittent (Fig. 4.12 (a)), but continuous (Fig. 4.12 (b)).



**Fig. 4.12** Unhygienic (a) and hygienic (b) and (c) welding to join plates.

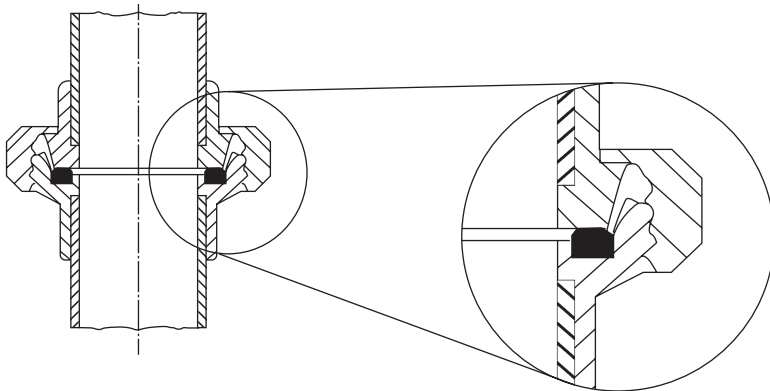
and (c)). Overlapped welded joints should be avoided since they retain soil and form 'dead' or 'shadow' areas at the overlap edge that are difficult to clean. If overlapping is unavoidable, it will be necessary to develop well-documented and adequate procedures for draining and cleaning these shadow areas. The welded seams should be ground flush and smooth. In the case of thick sheets the edge of the upper plate must be sloped. If necessary, edges must be ground. Figure 4.12(a) illustrates the problem with overlapping sheets, particularly if they are combined with an intermittent rather than continuous weld seam. Figure 4.12(b) shows an improved design with a sloped edge that is less likely to harbour residues and is easier to clean. Figure 4.12(c) shows an ideal design with smooth, continuously welded sheets. Welding in sharp corners of equipment must be avoided. Radiused corners (sloped sides) and welding seams away from corners are recommended (Fig. 4.5).

If adhesives are used for permanent joints they must be compatible with materials, products and cleaning/disinfecting agents with which they are in contact. All bonds should be continuous and mechanically sound so that the adhesives do not separate from the base materials to which they are bonded.

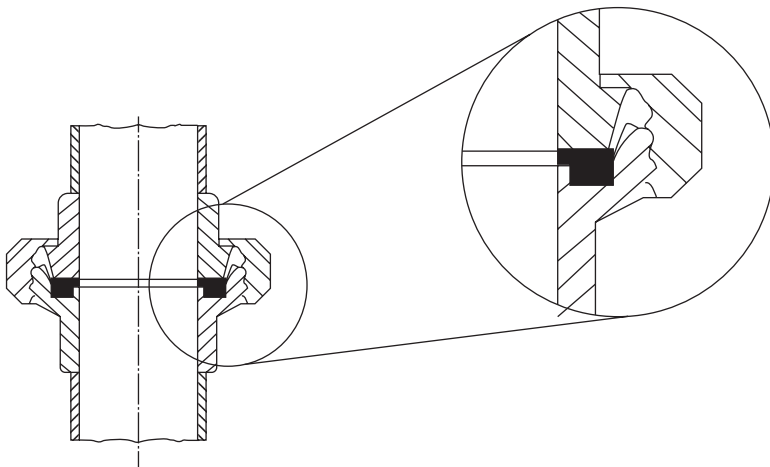
Metal-to-metal joints (other than welds) seal as a result of the deformation of the contacting metal surfaces. This causes permanent damage to these surfaces, making it more difficult to obtain a tight seal after every disconnection. Even when these joints are not visibly leaking, the ingress of microorganisms is possible. The seal obtained is also very unlikely to be at the product side and is more likely to follow an irregular line between

the inside and outside. The resulting annular crevice will trap product and create a hygiene risk. Metal-to-metal joints should therefore be avoided.

Dismountable joints (e.g. of plates or appendages) fixed by fasteners (e.g. screws or bolts) must only be used if dismantling is unavoidable. Where detachable joints are necessary, they should be sealed by elastomers (Baumbach *et al.*, 1997). Dismountable joints, such as screwed pipe couplings, must be crevice-free and provide a smooth continuous surface on the product side (Fig. 4.13). Flanged joints must be located with each other



Unhygienic design

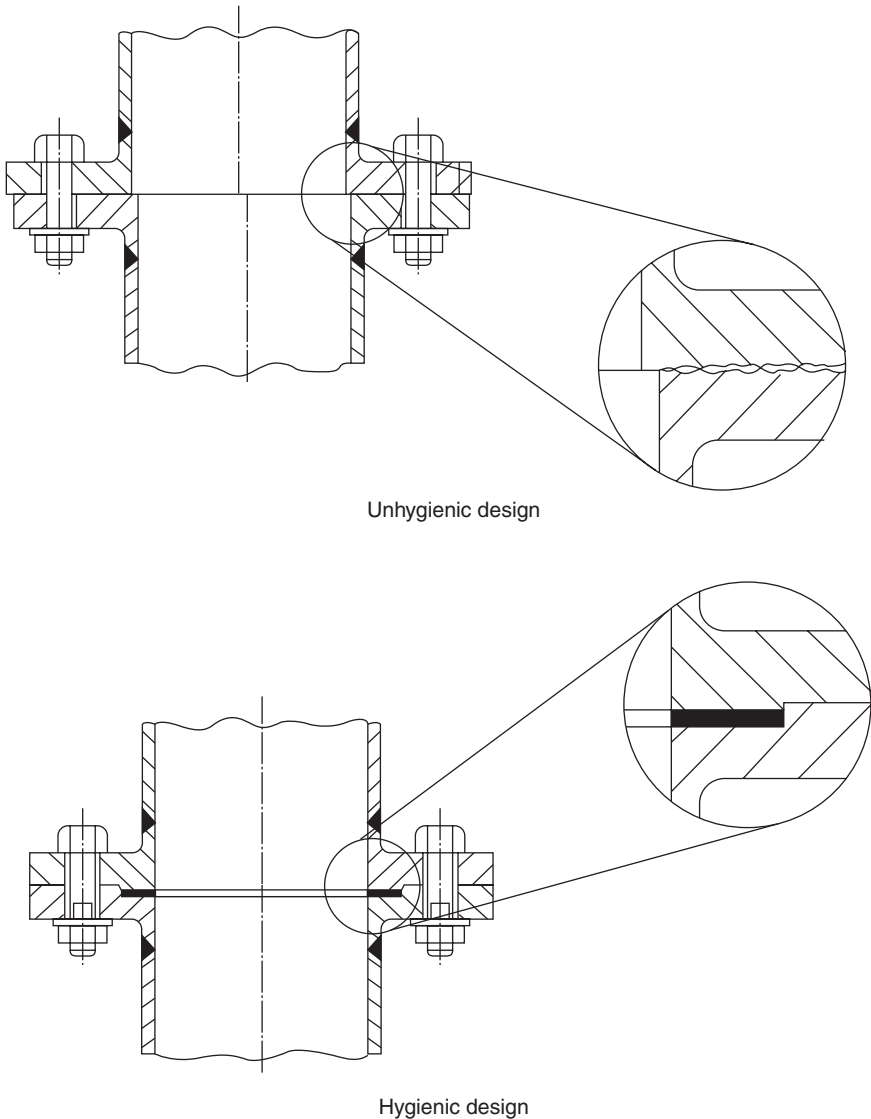


Hygienic design

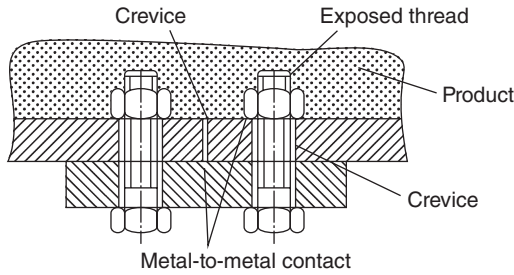
**Fig. 4.13** Hygienic and unhygienic screwed pipe couplings (DIN 11851).

and be sealed with a gasket because, although metal-to-metal joints can be made leak-tight, they may still permit the ingress of microorganisms (Fig. 4.14).

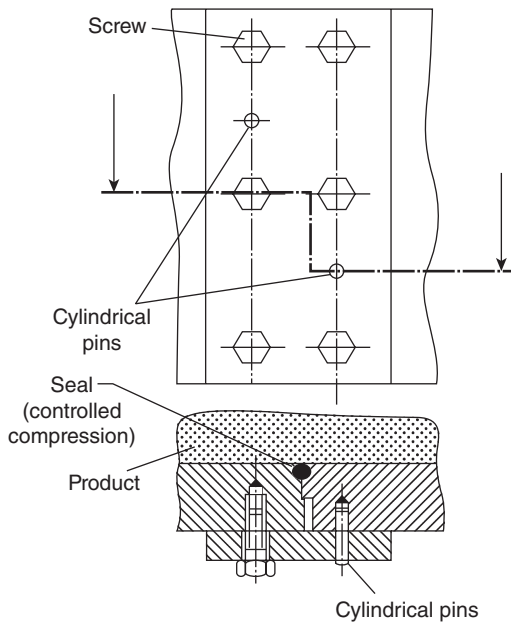
The sealing of metal-to-metal contact surfaces requires particular care. Figure 4.15 illustrates the problem of using overlapped screw joints. Screws or nuts are unable to provide sufficient compression to prevent crevices between sheet edges. Moreover, exposed screw heads and unsealed threads



**Fig. 4.14** Hygienic and unhygienic flanged joints in pipe couplings.

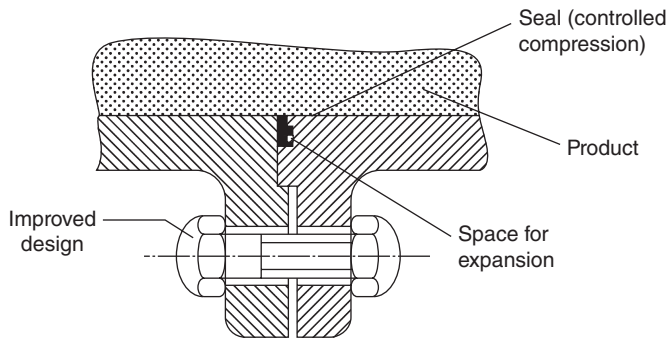


**Fig. 4.15** Poor design of joints.



**Fig. 4.16** Improved design of joints.

create additional hygiene hazards. An improved design is shown in Fig. 4.16 where the combined use of screws and pins provides improved compression and the two edges are properly sealed. In addition, screw and pin joints on the reverse side to the product remove the extra hazards shown in Fig. 4.15. However, the design of grooves for seals needs to allow space for the expansion of the seal into the product area during heating. A further improved design is shown in Fig. 4.17 using flanged sheets for controlled compression and allowing space for heat expansion. Seals are discussed in more detail later in the chapter.



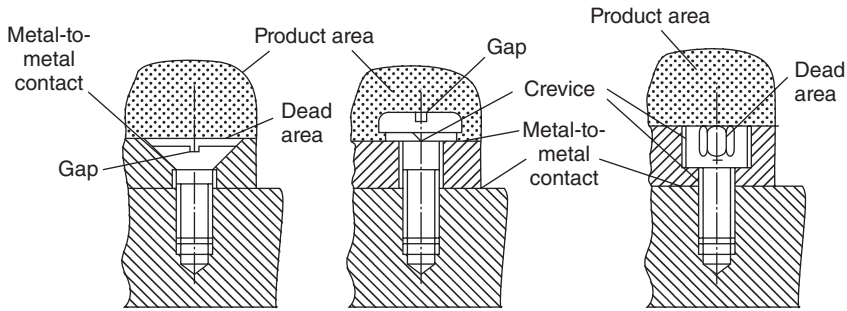
**Fig. 4.17** Further improved design of joints.

The welding of permanent joints should be done by trained and experienced welders following the appropriate guidelines (Barnickel *et al.*, 2006). Not all welding techniques can produce welds of a sufficient standard. Tungsten-inert-gas (TIG) welding should be used. To obtain a good weld, materials must match (in composition *and* in dimensions). During welding the materials must be fully protected by inert gas and the welding temperature must be correct. Otherwise, welds that may seem correct when fresh and polished will corrode rapidly in use. The preferred method for pipework is automatic orbital welding. If properly programmed, an orbital welding machine is capable of producing consistently high-quality welds.

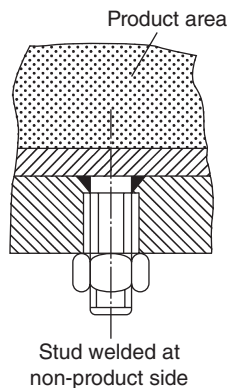
## 4.9 Fasteners

One of the most usual failures of sanitary design is the use of unsuitable fastenings such as nuts, bolts and screws (Hauser *et al.*, 2004b). Where possible on the product side welding must be used following the guidelines for hygienic welds. An acceptable alternative might be the use of adhesives. If adhesives are used, care must be taken to ensure that the seal obtained is reliable and can withstand process and cleaning conditions. Self-evidently the adhesive must be approved for food contact applications.

Fasteners present two problems. The first is the danger that they might work loose and fall into the product flow. If fasteners are unavoidable, they should ideally have magnetic properties so that downstream magnets as well as metal detectors have a chance to remove them. However, some types of stainless steel are less magnetic than others, and it may not always be possible to take this precaution. The second problem is the presence of metal-to-metal contact that, with increased wear, creates growing crevices



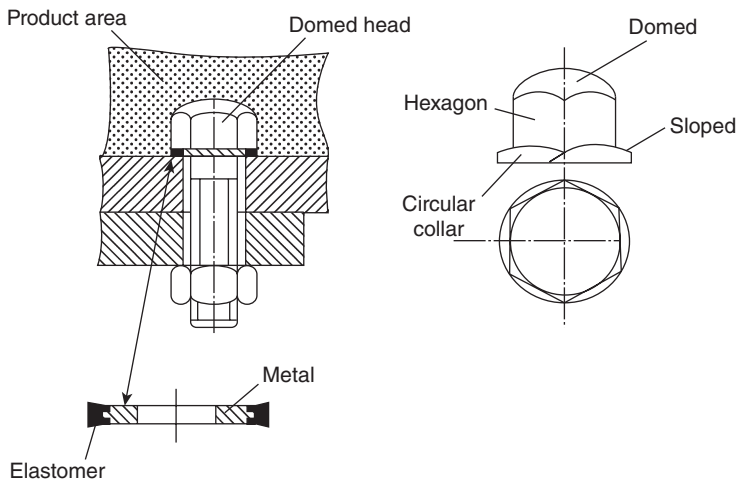
**Fig. 4.18** Hazards created by unhygienic use of screws.



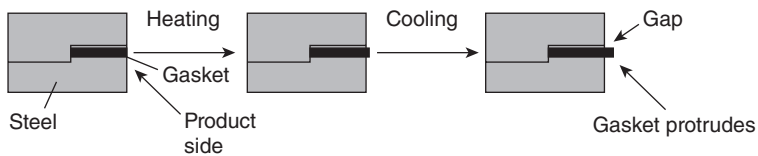
**Fig. 4.19** Hygienic use of screws: non-product side.

that will trap product residue. Fasteners also create dead spaces and other soil trap points. These are illustrated in Fig. 4.18.

If nuts or screws are unavoidable, they should be hygienically designed and installed (Anon., 1974). Ideally they should be inserted on the reverse side to the product (Fig. 4.19). If not, they should be designed with a domed head that minimises the risk of product adhering to the head and facilitates cleaning. Collars should also be circular and sloped. A metal-backed elastomer gasket should be used to seal the thread (Fig. 4.20). Rivets should not be used for joining surfaces. As equipment dismantling for cleaning, inspection and maintenance involves loosening of nuts and bolts, ease of removal is essential. Any potential thread seizure through over-tightening must be prevented and therefore selection of the nut and bolt material is important. If threads are damaged during dismantling, they should be immediately re-threaded or the damaged fastener replaced. Lubricants should be avoided as they may be a source of contamination.



**Fig. 4.20** Hygienic design of screws: product side.

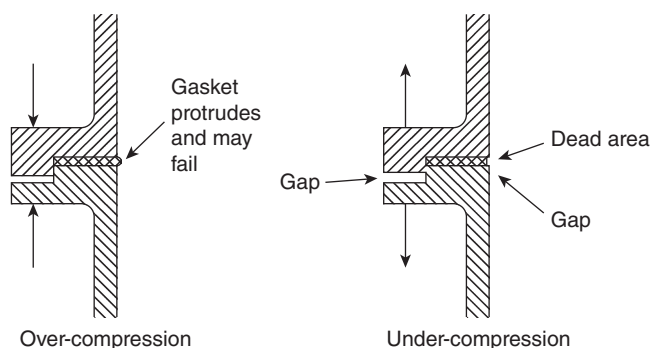


**Fig. 4.21** Deformation of non-resilient gasket material.

## 4.10 Seals

Seals have traditionally been made from rubber and particularly from synthetic rubbers or elastomers. Seals must be able to withstand a variety of conditions such as sub-zero temperatures during processing and temperatures above 100°C during sterilisation (Hauser *et al.*, 2007). Materials must also be easily cleaned during sanitation. They must also withstand a variety of products, such as acid and alkaline solutions as well as oils. To ensure a smooth durable surface with sufficient temperature and corrosion resistance, equipment manufacturers tend to use PTFE as gasket material in food processing equipment. PTFE, however, lacks resilience. It has an expansion coefficient of approximately  $100 \times 10^{-6}/\text{K}$ , compared to approximately  $16 \times 10^{-6}/\text{K}$  for stainless steel. Due to this large difference in thermal expansion coefficient between PTFE and stainless steel, a heat treatment changes the shape of the PTFE gasket and after cooling a crevice occurs (as shown in Fig. 4.21). For a gasket of 5 mm thickness and a temperature change from 20 to 120°C and back, the crevice may be 36 µm wide if there is no resilience at all (in practice the gap will be slightly smaller). It is important not to use seals made from non-resilient materials (Lelieveld, 1994).



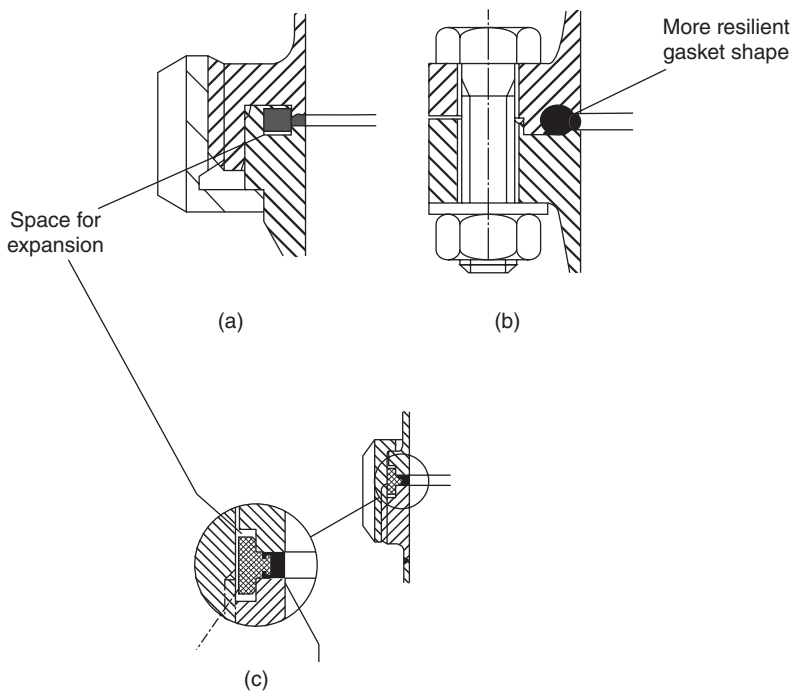


**Fig. 4.22** Over- and undercompression of gasket material.

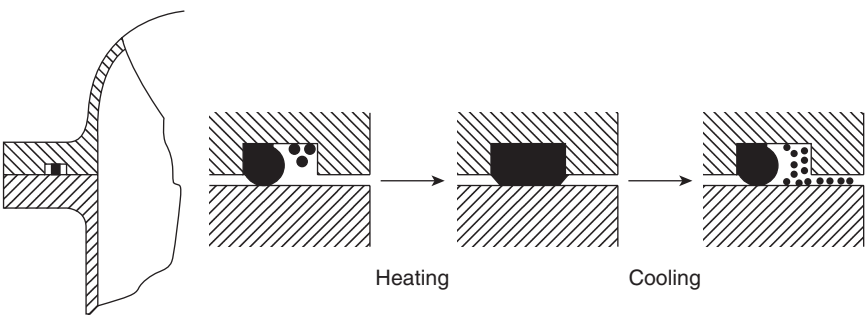
As well as selecting appropriate materials, it is also important to control compression of elastomers. Overcompression may lead to destruction of the elastomer, particularly if the overcompressed elastomer is heated (for example, in pasteurisation and sterilisation processes). The elastomer may become brittle and fail to provide the required seal, while parts of the elastomer may contaminate the product. Secondly, overcompression may lead to protrusion of the elastomer into the equipment (Fig. 4.22), thereby hampering cleaning and draining. Undercompression is also a potential problem as it may lead to crevices and fail to provide a reliable seal (Fig. 4.22). Even when it is not visibly leaking, the seal may permit the ingress of microorganisms. Pipe coupling needs therefore to take account of gasket compression as well as other factors such as control of alignment (Baumbach *et al.*, 1997). Figure 4.23 shows designs that ensure control of the compression of elastomers. Figure 4.23(c) shows an ISO 2853 coupling which uses a T-gasket design to control compression (Anon., 1976; Hauser *et al.*, 2007).

Installations containing conventionally designed o-ring seals invariably create crevices that are impossible to clean in place and provide dead spaces in which microorganisms can multiply. This problem is a consequence of the different thermal expansion coefficients of elastomers and steel. Heat causes the o-ring to expand, protecting microorganisms trapped between the o-ring and the steel surface against contact with hot water, chemical solution or steam. After cooling down and shrinkage of the o-ring, the survivors will be freed and will infect the product that will fill the gap at the start of the production (Fig. 4.24).

O-rings can only be used if mounted in a way that ensures that the area of steel covered by the rubber at the product side is not influenced by thermal expansion. Often this leads to large forces inside the o-ring and as a result the lifetime of the o-ring may be reduced significantly. Figure 4.25 illustrates hygienic design using o-rings. Figure 4.25(a) shows a pipe coupling

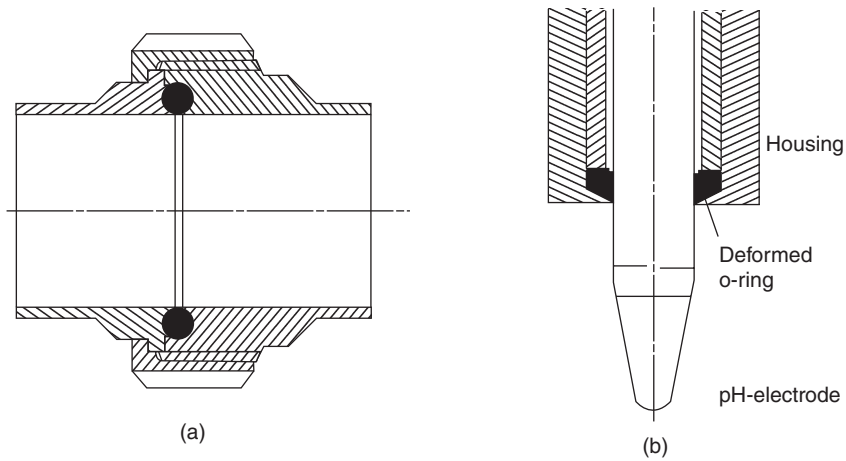


**Fig. 4.23** Hygienic design of pipe couplings controlling both alignment and compression.

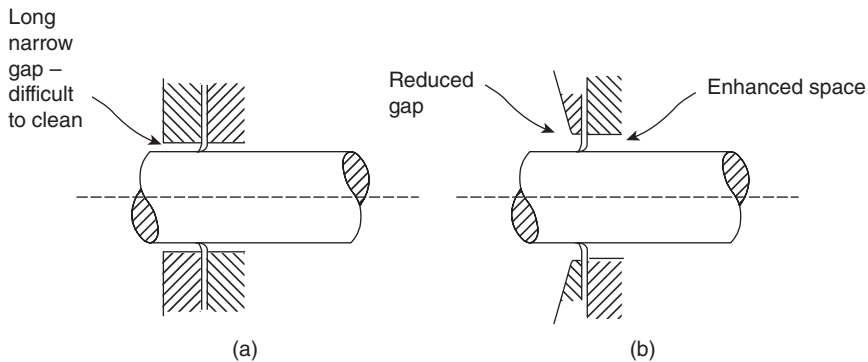


**Fig. 4.24** Unhygienic o-ring seal.

and Fig. 4.25(b) shows a pH-electrode fitting. In both cases the o-ring is almost completely enclosed with the surrounding metal partially protected from the product contact surface. However, because of the volume of the elastomer, its virtually complete enclosure and the differences in expansion between elastomer and steel, forces inside the elastomer may result in accelerated ageing, so that periodic replacement may be required.



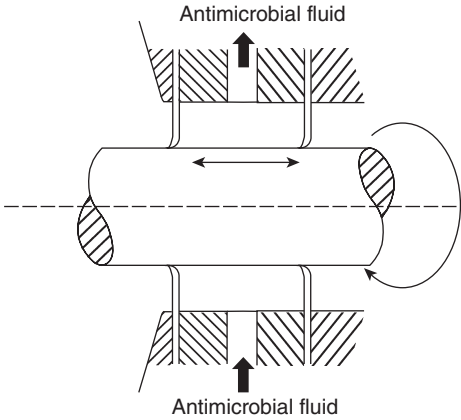
**Fig. 4.25** Hygienic use of o-rings in a pipe coupling (left) and a sensor (right).



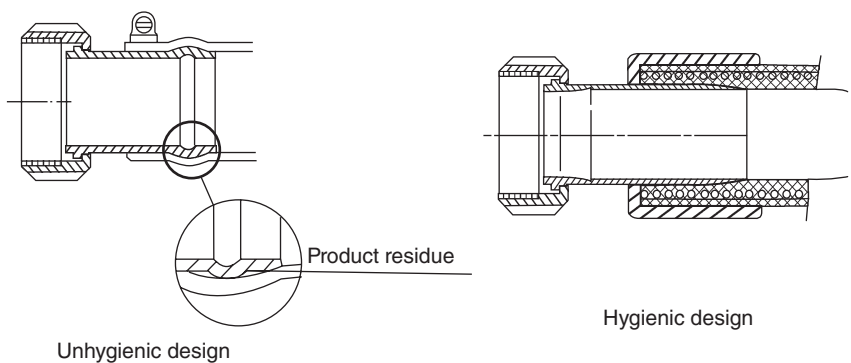
**Fig. 4.26** Hygienic and unhygienic design of dynamic seals.

The use of metallic stops would ensure bacteria-tightness but avoid destruction of the elastomer during heating.

Dynamic seals also require careful hygienic design so that they can be easily cleaned. The space around the seal should be as wide as possible. The narrow annular space that is usually found at the product side of the seal must be avoided. Figure 4.26(a) illustrates the problem, whilst Fig. 4.26(b) illustrates a design that both reduces the volume of annular gap around the shaft and ensures sufficient space around the seal. Since they will still allow the passage of some microorganisms, dynamic seals should be avoided in aseptic equipment. This may be achieved by using bellows or diaphragms that separate the seal from the product side. Where that is not possible (e.g. in the case of rotary seals), double seals must be used (Fig. 4.27). The space



**Fig. 4.27** Hygienic design using a double seal.



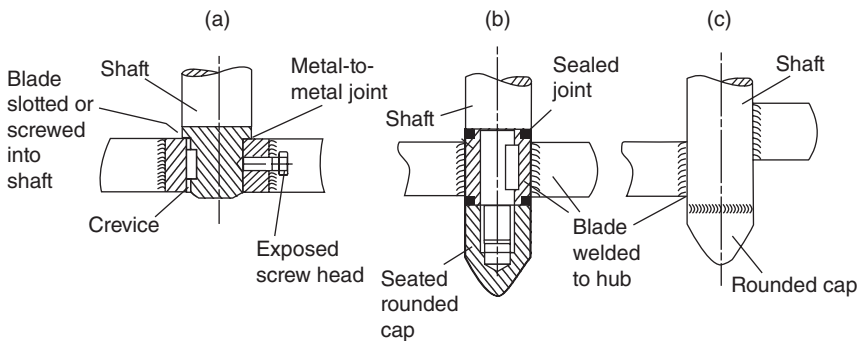
**Fig. 4.28** Hygienic and unhygienic joints for flexible hoses.

between the seals must be flushed either with an antimicrobial fluid (such as hot water, steam or a solution of an antimicrobial chemical) or with sterile water. The choice of flushing fluid will depend on product requirements. To avoid the transfer of microorganisms from the outside of the equipment to the inside, without a sufficiently long exposure to the antimicrobial fluid, the distance between the two seals must always be larger than the stroke of the reciprocating shaft. It should be realised that rotating shafts often exhibit some axial mobility and hence assist penetration of microorganisms. Flexible hoses are frequently used to connect moving and static parts of process lines (e.g. moveable dosing heads on filling machines). Figure 4.28 shows the non-cleanable crevice created by the traditional way of mounting hoses to pipes and how this can be done correctly without crevices.

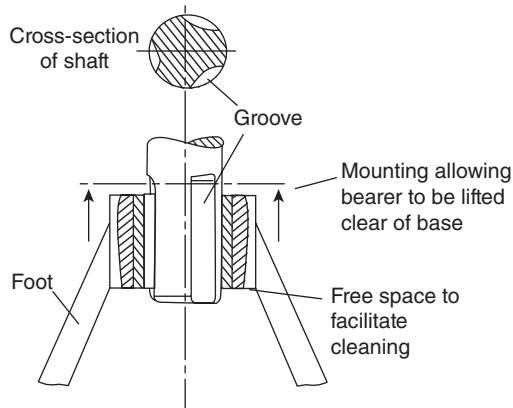
### 4.11 Shaft ends

Equipment such as stirrers, homogenisers, mixers or cutters can pose a significant risk (Timperley and Timperley, 1993). Crevices caused by metal-to-metal contact or dead spaces in grooves must be avoided. If adhesives are used for metal-to-metal joints, they and the bonds created by their use must follow the recommendations given for permanent joints (see Section 4.8). Hubs, nuts and coupling shafts must be carefully sealed under controlled compression. Corners (e.g. hubs and nuts) must be radiused and horizontal areas sloped. To avoid any screwed joints, appendages (such as blades) should be welded to the hub. Figure 4.29 illustrates good and bad hygienic design of a blade attachment. Design (a) employs metal-to-metal contact, creating crevices, and uses exposed screw heads, which both will harbour microorganisms. Design (b) shows a hygienically designed detachable blade attachment with a sealed, sloping cap and joints. Design (c) illustrates a welded blade attachment with a sloping cap that facilitates cleaning.

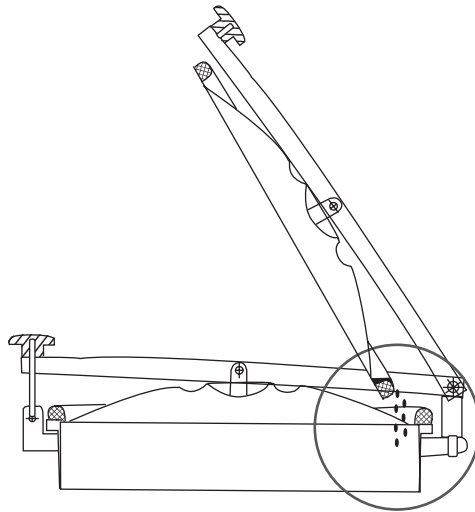
Bearings should, wherever possible, be mounted outside the product area to avoid possible contamination of product by lubricants (unless they are edible) or possible failure of the bearings due to the ingress of the product. Shaft seals must be of such design so as to be easily cleaned and, if not product lubricated, then the lubricant must be edible. Where a bearing is within the product area, such as a foot bearing for an agitator shaft in a vessel, it must be mounted clear of the base to allow free cleaning of the feet. It is also important that there is a groove completely through the bore of the bush, from top to bottom, to permit the passage of cleaning fluid. Figure 4.30 illustrates a hygienic design for a foot bearing with grooves in the bearing area to facilitate lubrication by fluid products and cleaning operations, and mounted clear of the base.



**Fig. 4.29** Unhygienic (a) and hygienic (b and c) design of blade attachments.



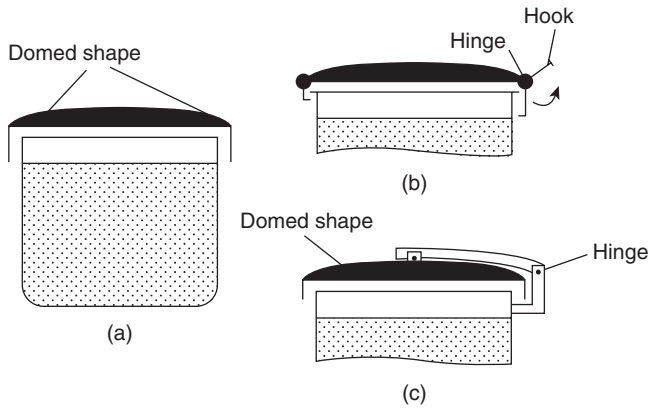
**Fig. 4.30** Hygienic design of a foot bearing.



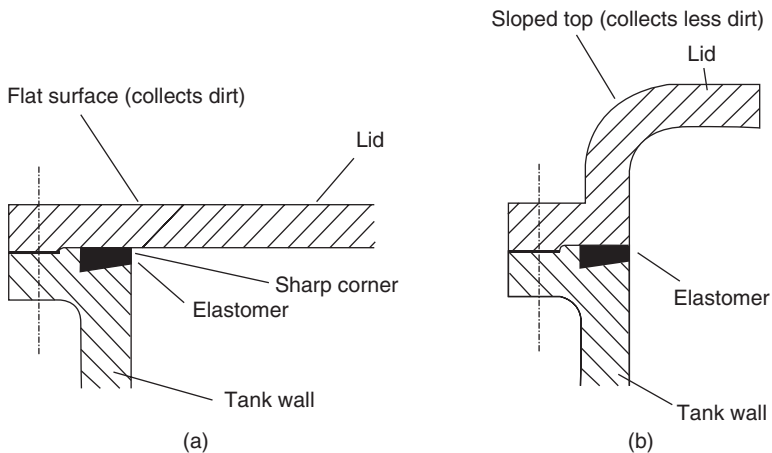
**Fig. 4.31** Example of a cover design that results in contamination of the product when opened.

## 4.12 Doors, covers and panels

Doors, covers and panels should be designed so that they prevent the entry and/or accumulation of soil. Where appropriate they should be sloped to an outside edge and should be easily removed to facilitate cleaning. Figure 4.31 shows how a lid of a vessel, intended to protect a product, may accumulate dirt that will contaminate the product in the vessel when the lid is opened. Figure 4.32 illustrates more hygienic designs. Covers can be

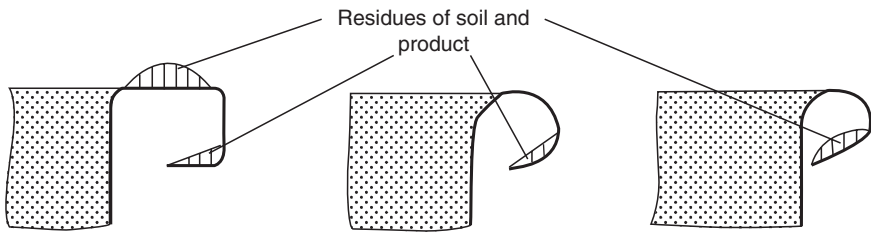


**Fig. 4.32** Hygienic designs for equipment covers.

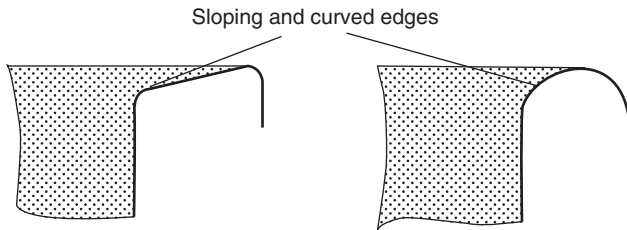


**Fig. 4.33** Unhygienic (a) and hygienic (b) mounting of lids.

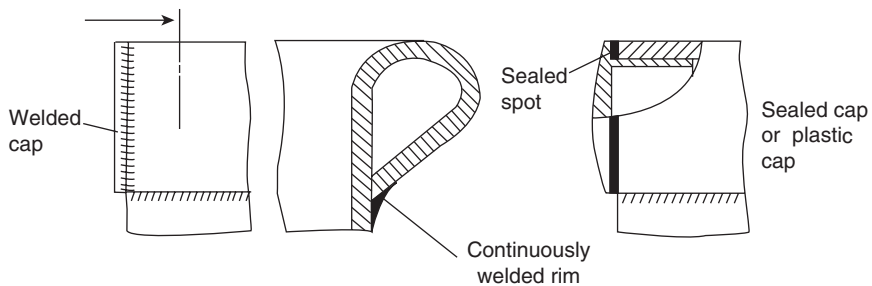
completely detachable for cleaning, as in Fig. 4.32(a) and (b). Non-removable covers must be sloped for drainage (Fig. 4.32(c)). If hinged covers are used, the hinge must be designed in such a way that it can be dismantled or cleaned easily and that accumulation of product, dust and foreign bodies (including insects, etc.) is avoided. Pipes or instruments attached to or passing through covers must be welded or carefully sealed. Figure 4.33 illustrates an incorrect (a) and correct (b) way of mounting a lid. Design (b) has a sloped top that avoids the sharp corner created by design (a) in the closed position, which would be difficult to clean. Tanks should not be opened at all during production unless absolutely necessary.



**Fig. 4.34** Unhygienic rim designs.



**Fig. 4.35** Hygienic design of rims.



**Fig. 4.36** Sealed rims and caps.

### 4.13 Rims

The design of top rims of product-containing equipment (e.g. containers, chutes, boxes) must avoid ledges where product can lodge and which are difficult to clean (Fig. 4.34). Open top rim designs must be rounded and sloped for drainage (Fig. 4.35). If the top rim is welded to the wall, the weld must be flush and polished to provide a smooth surface. In this case, the rim must be totally closed. Any holes, therefore, must be sealed by welding or by fitting sealed caps (Fig. 4.36) (Hauser *et al.*, 2004b).

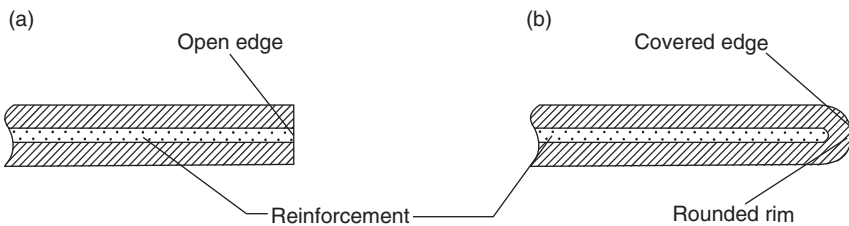
### 4.14 Conveyor belts

Conveyor belts present particular problems in hygienic design. It is very important to ensure that a conveyor belt does not absorb moisture as this

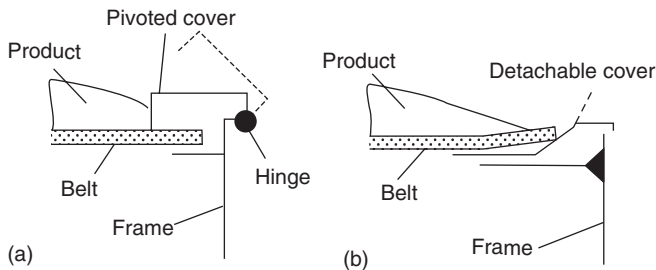


will lead to microbial growth and contamination. Once microorganisms have colonised the inner fabric of the belt, it will be impossible to remove or inactivate them without destruction of the belt. Accumulation of soil around the edges of the belt must also be avoided, which requires a special construction. Even with proper design, thorough cleaning and inspection after cleaning is essential as spillage around the edges is very difficult to prevent completely (Hauser *et al.*, 2004b).

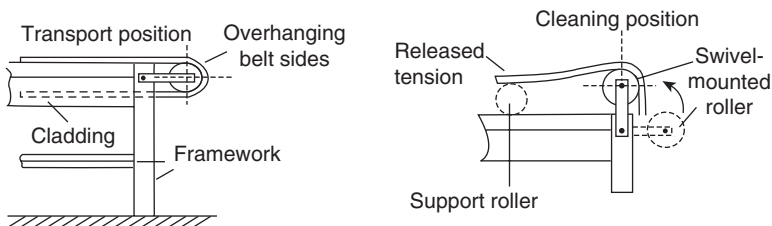
Figures 4.37–4.41 illustrate a number of design issues. Open edges of reinforced belts cause hazards by crevices or absorption of liquids (Fig. 4.37(a)). Reinforced materials should therefore be encased within the main belt with the use of rounded edges for easier cleaning (Fig. 4.37(b)). Non-removable bearing surfaces for belts and non-removable covers allow dirt to accumulate and prevent cleaning. Pivoted covers with hinges also create crevices and are difficult to clean (Fig. 4.38(a)). A design with a detachable



**Fig. 4.37** Unhygienic (a) and hygienic (b) design of conveyor belt material.



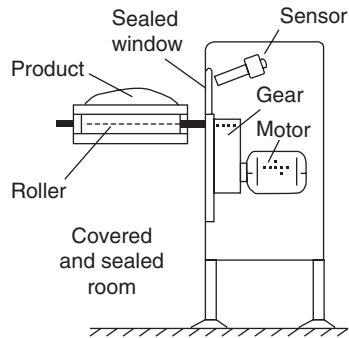
**Fig. 4.38** Unhygienic (a) and hygienic (b) cover design of conveyor belts.



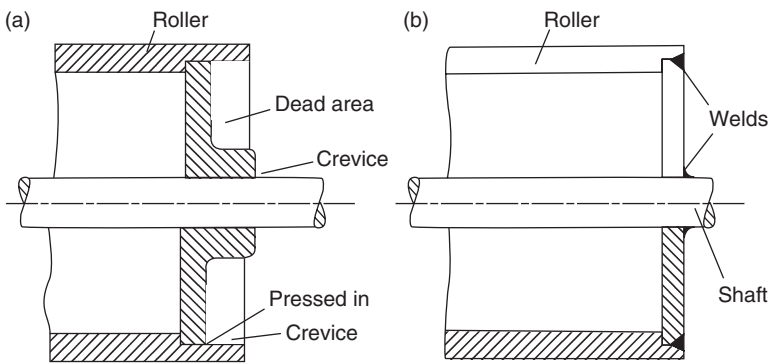
**Fig. 4.39** Swivel-mounted rollers for conveyor belts to allow cleaning.

cover that can be removed for cleaning is preferable (Fig. 4.38(b)). The use of swivel-mounted rollers also facilitates cleaning. When the conveyor belt is not in use, the rollers can be raised to create a space between the belt and the bearing table, which will allow cleaning to take place (Fig. 4.39). To avoid any hygiene risk, drives of belts and any appendages such as sensors must be covered, and the belt should be clear of framework to give open access to the belt and rollers for cleaning (Fig. 4.40). Sides of rollers which are not aligned and smooth cause dead areas and crevices (Fig. 4.41(a)); aligned front sides which are properly welded to the roller and to the shaft avoid any hazard and can be cleaned easily (Fig. 4.41(b)). Hygienically designed drum motors may also be considered, because they avoid the need of an external drive (Fig. 4.42).

Open plastic modular belts tend to be more difficult to clean, in particular because of the crevice between the connecting rods and the belt. Modern designs for the food industry use oblong openings for the (round) rods, creating room for cleaning. Figure 4.43 is an example of such a construction.



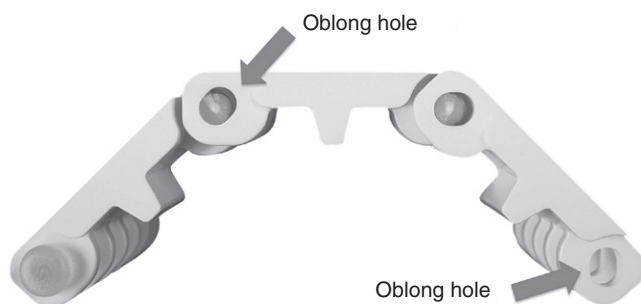
**Fig. 4.40**    Sealed casing for conveyor belt drives and monitoring equipment.



**Fig. 4.41**    Hygienic and unhygienic design of rollers for conveyor belts.



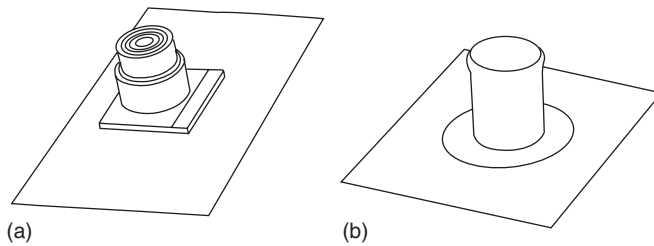
**Fig. 4.42** Example of a drum motor (courtesy of Interroll).



**Fig. 4.43** Open plastic modular belt for food contact applications, with space between the connecting rod and the holes in the belt to facilitate cleaning (courtesy of Habasit).

## 4.15 Equipment controls and instrumentation

Controls, particularly those that are repeatedly touched by food handlers to allow process operation, should be designed to prevent the ingress of contamination and should be easily cleanable. Pathogenic microorganisms have been known to harbour in switches and be transferred to product every time they are opened (Holah, 2002). The importance of good hygienic design can be illustrated with reference to a sliced-meat factory, which had



**Fig. 4.44** Unhygienic (a) and hygienic (b) design of control switch button.

slicers whose action was initiated by pressing a control switch identical to that shown in Fig. 4.44(a). The factory concerned was having problems due to product contamination with *Listeria monocytogenes*, and was eventually forced to stop production for a few days with a subsequent financial loss in excess of £1 million. The problem was finally traced to a source of *L. monocytogenes* that was being harboured within the body of the slicer switches. At the beginning of production the slicing operative picked up a log of meat, placed it on the slicer and pressed the control switch to start slicing. From this point on, and every time he subsequently repeated this procedure, *L. monocytogenes* was transferred from his hand to the slicer and, by the middle of the shift, sufficient *L. monocytogenes* was present on the slicer to be detected in the product. The conclusion to the incident was the purchase of a number of rubber switch covers as shown in Fig. 4.44(b) for the cost of a few pounds.

Instruments must be constructed from appropriate materials. If they contain a transmitting fluid, such as in a bourdon tube pressure gauge, then the fluid must be approved for food contact. Many instruments themselves are hygienic but often they are installed unhygienically (Berrie, 2001). When choosing instrumentation for food production, it is always wise to bear in mind that it is not the normal operation of a device that gives problems, but rather the unexpected event. Thus, the risk of chemical contamination can be eliminated by using a suitable material for the wetted parts of the device. The risk of bacterial contamination can be reduced by regular cleaning and the use of suitably designed process connections. The introduction of foreign bodies, however, is only partially covered by the adoption of a high degree of protection. The case where equipment in direct contact with the product fails, producing debris or releasing contaminants, must also be considered. Here it is essential that the user is warned and/or that the released products are not dangerous to health.

The wetted parts of a device are those parts that are in contact with the medium being measured. For temperature measurement this might be the thermowell, for pressure measurement the isolating diaphragm and for a contacting level measurement the sensing element itself. Even so-called noncontact devices must be considered to have wetted parts when they

intrude into the pipeline or tank. Here it is not so much the contact with the medium, but crevices and their exposure to high temperatures and vapours that have to be considered. The positioning of the measurement device must also be examined. Flowing gases, liquids or solids may cause abrasion or generate high mechanical forces, which combined with high temperature or vibration enhance electrochemical attack or mechanical fatigue. Moreover, the wetted parts must be able to withstand the forces and temperatures generated during cleaning or sterilisation-in-place procedures.

In addition to the normal mechanical design factors, the toxicological and bacteriological compatibility of the materials used for wetted parts must also be taken into consideration. As far as the toxicological properties are concerned, materials should comply with the relevant regulations, such as in the EU for plastic materials, regulation EC 10/2011. Where guidance is not available in the EU, the requirements of the USA Food and Drug Administration on food contact materials (FDA CFR-21) can be used (see Chapter 1).

The bacteriological factor is a different matter. Although regular cleaning and gap-free design reduce the broad risk of infection, the proper design and finishing of the wetted parts is just as important. This basically means flowing contours and clean welding, no nooks and crannies, and no obstructions that might cause the product to gather and rot. Usually all components in the tank are of highly polished stainless steel to prevent the product from sticking.

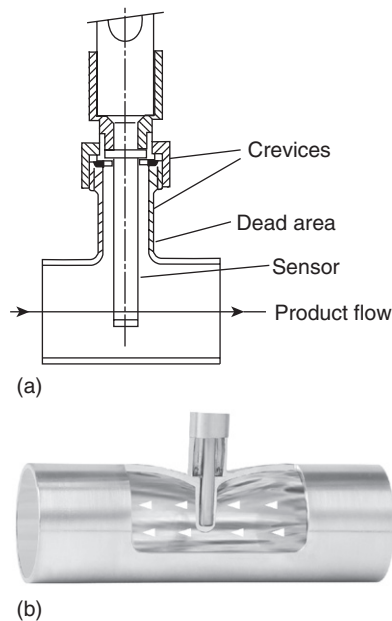
The corrosion resistance of the wetted parts is also important. This is not simply a matter of their resistance to the products and cleaning agents. Under high temperatures, strong vibration and mechanical stress, electrochemical corrosion or intergranular corrosion may be enhanced. The one results in surface pitting, providing an ideal breeding place for bacteria, the other in the depletion of the nickel and chromium at the grain interfaces, which means the component will rust. Table 4.2 lists some stainless steels suitable for the food industry.

The majority of process instruments are installed in pipes or tanks by means of threaded connections or flanges. Neither of these methods is suitable for food manufacture since both offer crevices and gaps where the product can accumulate and decay (Fig. 4.45(a)). In addition, the mounting and dismounting take considerable effort, so cleaning becomes difficult. Ideally, a process connection should offer no gaps where the product can become trapped. One solution is to weld the instrument in place and then grind and polish the inside of the connection. Unfortunately this means that the instrument cannot be exchanged should it fail. For thermowells, where the sensor insert is easily replaced (Fig. 4.45(b)), and for flowmeters, however, it is quite feasible and is often encountered. Pressures and temperatures can also be measured without sensors protruding into the pipeline, as shown in Figs. 4.45(c) and Fig. 4.46. Here instead of the

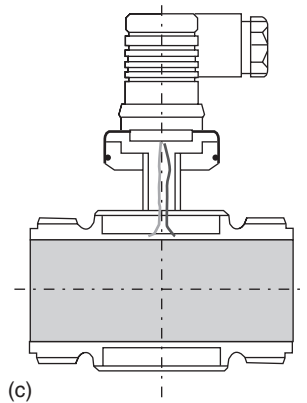
**Table 4.2**    Stainless steels suitable for the food industry

Material	AISI*	Properties
1.4301	304	Good resistance against organic acids at moderate temperatures Good resistance against salt and alkalis at moderate temperatures
1.4404	316L	Increased resistance against non-oxidising acids such as acetic acid, tartaric acid, phosphoric acid Increased resistance against pitting and intercrystalline corrosion
1.4435	316l	Better corrosion resistance than Type 1.4404
1.4571	316 Ti	Increased corrosion resistance against particular acids and salt water Resistance against pitting corrosion

\* The AISI steels are equivalents but do not have identical compositions.



**Fig. 4.45**    Unhygienic (a) and hygienic ((b) and (c)) mounting of a temperature sensor. (b) is courtesy of Wika.



(c)

**Fig. 4.45** *Continued***Fig. 4.46** Example of a hygienic device for measuring temperature and pressure in a food process pipeline (courtesy of Wika).

temperature in the centre of the pipe, the temperature of the wall is measured, which often is the lowest temperature and therefore during, for example, in-line heat treatments, microbiologically more relevant. For the pressure, the expansion of the pipe is measured, where the pipe wall has been reduced to make this accurately enough possible. Process instruments are generally installed by means of so-called sanitary couplings. These combine the need for a gap-free mounting with that of easy mounting and dismounting, allowing them to be quickly removed for cleaning. Over the years a number of different designs have come on the market, a selection of which are summarised in Table 4.3. More detailed information can be found in EHEDG Test Methods Subgroup (2011).

**Table 4.3** Sanitary couplings for the food industry

Type	Use	Description
Dairy coupling (to DIN 11851)	Pipes and tanks	Reasonably priced coupling that is frequently found in the food industry. Its weakness lies in the hygienic adaptation to the process which does not allow flush mounting. The coupling is made by a threaded boss and slotted sleeve. A conical seating and tapered nozzle with sealing ring comprise the process seal
Aseptic coupling (to DIN 11864)	Pipes (tanks in preparation)	Introduced in 1998 as a replacement for the dairy coupling. Designed to EHEDG recommendations, thanks to a flush sealing construction. The mechanical coupling is via bolts or a threaded sleeve, the seal being flush with the pipe wall
Varivent® coupling	Pipes	In-line housing that allows the flush mounting of the sensor, which is attached to the housing by means of a screw clamp. Three housing types cover a wide range of pipe diameters. For the majority of process sensors Type 3, for pipes of DN 40 upwards, is required. This facilitates the exchange of instruments
APV coupling	Pipes	In-line housing of similar construction to the Varivent coupling. The sensor, however, is bolted in position
SMS coupling	Pipes and tanks	Reasonably priced, Scandinavian standardised screw coupling which is also used in France. Its weakness lies in the hygienic adaptation to the process which does not allow flush mounting
IDF coupling	Pipes and tanks	International Dairy Federation screw coupling standardised in ISO
Tri-clamp® coupling	Pipes and tanks	Sanitary coupling with bevel seating produced by the Tri-Clover Company in America. Instruments are quickly mounted and fixed with snap-on clamps. The couplings find widespread use in America



**Table 4.4** Ingress protection categories to IEC 60 529

Code	Ingress protection against protection against solids water	Code	Ingress
	Not protected	0	Not protected
0	≥50 mm diameter, e.g. hand	1	Vertical dripping
1	≥12.5 mm diameter, e.g. finger	2	Dripping (15° inclination)
2	≥2.5 mm diameter, e.g. tool	3	Water spray
3	≥1 mm diameter, e.g. wire	4	Splash water
4	Protected from dust	5	Jet of water
5	Dust-proof	6	Strong jet of water
6		7	Temporary submersion
		8	Total submersion

**Table 4.5** Degree of protection of enclosures as per NEMA Standard 250 (selection)

Type	Indoor	Outdoor	Degree of protection
1	yes		Protection against contact with equipment within the housing
2	yes		Protection against a specified quantity of water droplets and dirt
3		yes	Protection against blown dust, rain, sleet and snow, and external ice formation
4	yes	yes	Protection against blown dust, splashes and jets of water
4X	yes	yes	Protection against corrosion, blown dust, splashes and jets of water
5	yes		Protection against dust falling, dirt and lubricating non-corrosive fluids
6	yes	yes	Protection against water penetration during occasional temporary submerging in limited depth

Just as important as the wetted parts and process connection is the design of the housing of a process instrument. Depending upon the instrument type, this may contain only the connecting terminals or the entire evaluating electronics. In both cases it must provide protection:

- from the ingress of dust or moisture from the outside;
- when the sensor is used in an explosion hazardous area, from the egress or a spark or flame from the inside to the outside.

As far as the ingress of dust and moisture is concerned, the world is divided into two camps. One half uses the IP standard (IEC standard 60 529) and the other the American NEMA Standard No. 250. Nowadays, however, many manufacturers quote both in their technical specifications.

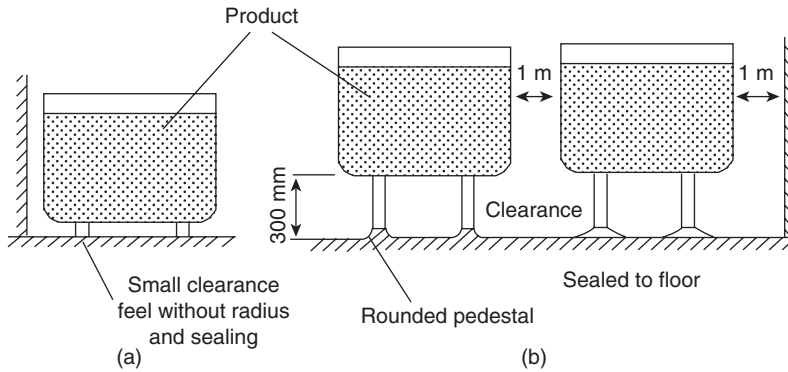
The IP standard is a description of the measures designed for the protection of the housing and the equipment within the housing. The degree of protection is indicated by a two-part code, e.g. IP 65. The first number is concerned with the protection from the ingress of solid matter, the second with water. As can be seen from Table 4.4, in order to withstand the frequent cleaning in a food production facility, housings with ratings of IP 65 or better are required. The NEMA standard comprises 14 type codes that deal with practical requirements on housings suitable for indoor and outdoor use. It also makes a statement about the protection from external influences and conditions such as mechanical impact, corrosion, humidity, mould, pests, dust, etc. As can be seen from Table 4.5, which lists only a selection of codes, a NEMA 4X enclosure is best suited to the requirements of the food industry.

In comparison to the chemical industry, there is less need for explosion protection in the production of food. If flammable liquids or easily ignitable gases are present, however, then the instrumentation must be approved for use in explosion hazardous areas. Powders can also be a problem, since clouds of dust are easily combustible under certain conditions. For milling, storage, conveyance and bagging operations, therefore, the Dust-Ex equipment should be used. The types of explosion protection are standardised in EN 50 014.

#### **4.16 Equipment installation**

The potential for well-designed and constructed equipment to be operated in a hygienic manner may be easily vitiated by inadequate attention to its location and installation (Thorpe and Barker, 1987). Timperley (1997), when considering the accessibility of equipment, recommended that it is more effective to consider complete lines instead of individual items of equipment and recommended the following:

- There should be sufficient height to allow adequate access for inspection, cleaning and maintenance of the equipment and for the cleaning of floors. A minimum of 300 mm is recommended.
- All parts of the equipment should be installed at a sufficient distance from walls, ceilings and adjacent equipment to allow easy access for inspection, cleaning and maintenance, especially if lifting is involved. A minimum distance of 1 m is recommended, though 2 m is often seen as a more practical minimum.
- Ancillary equipment, control systems and services connected to the process equipment should be located so as to allow access for maintenance and cleaning.
- Supporting framework, wall mountings and legs should be kept to a minimum. They should be constructed from tubular or box-section



**Fig. 4.47** Unhygienic (a) and hygienic (b) mounting of equipment.

material which should be sealed to prevent ingress of water or soil. Rounded pedestals are also acceptable. In both cases, the base for such supports should be sloped to facilitate drainage and cleaning. Angle- or channel-section material should not be used.

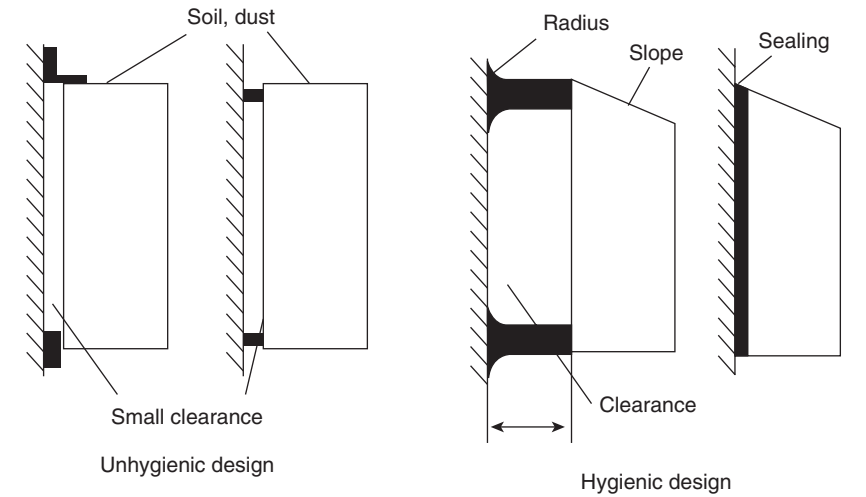
- Base plates used to support and fix equipment should have smooth, continuous and sloping surfaces to aid drainage and cleaning. They should be coved at the floor junction. Alternatively, ball feet should be fitted.
- Pipework and valves should be supported independently of other equipment to reduce the chance of strain and damage to equipment, pipework and joints.
- Once installed, a series of maintenance measures should be put in place to ensure the required level of equipment hygiene is maintained for the equipment during its specified life.

Figure 4.47 illustrates examples of poor (a) and good (b) hygienic design using these principles. The risk of condensation on equipment, pipework and the fabric of the building should be avoided. If unavoidable, the design should be such that condensate is diverted away from the product. Supports for piping or equipment must be fabricated and installed such that no water or soil can remain on the surface or within the supports. The possible adverse galvanic reactions between dissimilar materials should be taken into consideration. It is also important to avoid steps due to misalignment in equipment and pipe connections that might harbour water or soil.

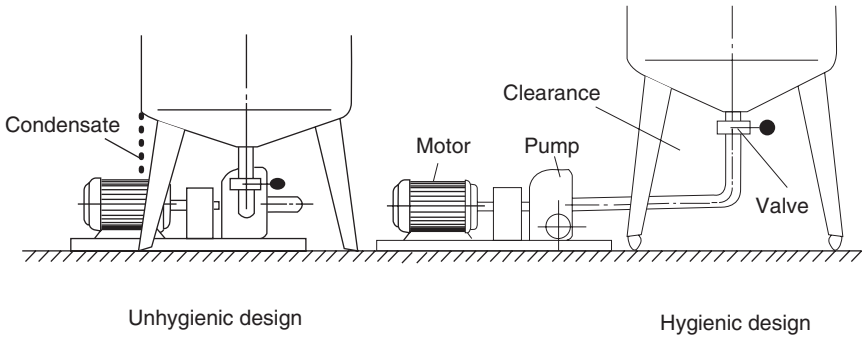
With equipment that is fixed to walls, any horizontal surfaces or the ledges of fasteners can retain soil, and a small clearance hampers cleaning between the wall and the equipment from the wall. Horizontal supports should be radiused and properly fixed to the wall, ensuring sufficient clearance. Alternatively, equipment can be fixed to the wall using sealing materials (Fig. 4.48). Equipment must not be mounted beneath tanks or

vessels so that maintenance and cleaning are not possible. Accessible equipment can be more easily maintained and gives open space for handling and cleaning beneath tanks and sufficient clearance (Fig. 4.49).

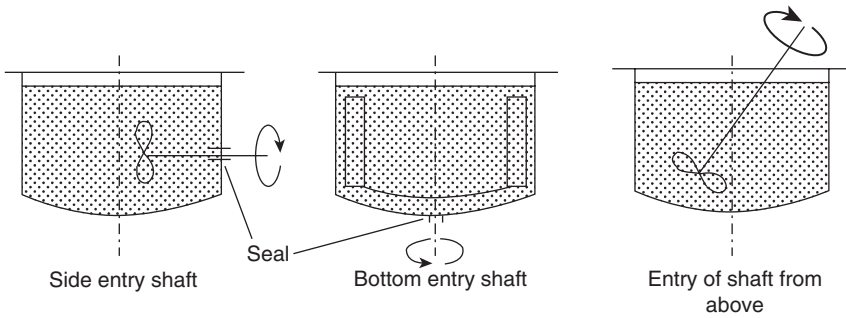
Apparatus such as stirrers, homogenisers or mixers should preferably be arranged in such a way that sealing of shaft passages in the product area is avoided by mounting them above the product area (Fig. 4.50). In the case of arranging the motor drive above the product it should preferably be placed beside the equipment (Hauser *et al.*, 2004b). The possibility of contamination by lubricants and soil from the motor or gearbox entering the product area must be avoided by using drip trays in combination with thrower rings on the shaft (Fig. 4.51). The motor should be covered by a



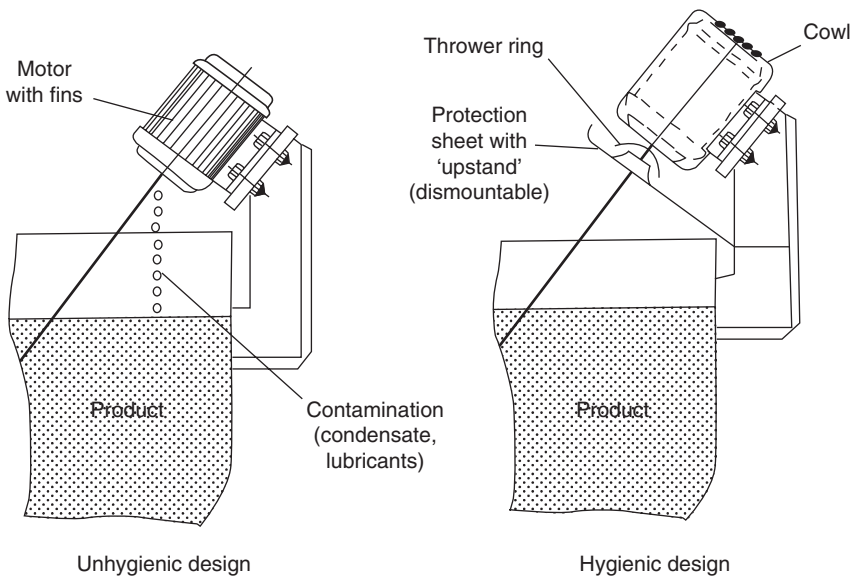
**Fig. 4.48** Hygienic and unhygienic mounting of equipment on walls.



**Fig. 4.49** Hygienic and unhygienic positioning of equipment beneath tanks.



**Fig. 4.50** Hygienic design of shafts.



**Fig. 4.51** Hygienic and unhygienic mounting of equipment above product.

hygienically designed cowl. If shaft passages are unavoidable, dynamic seals must be used; see above and Figs. 4.26 and 4.27.

Mesh, screens, grids or perforated sheets should be avoided in the product area. Application for guarding or for processes such as sieving and drying requires particular attention to ensure cleanability. Special, fully (vacuum) welded gridirons are available, avoiding any dead areas. A potential risk of cabling is contamination caused by the collection of dirt and dust as well as microbial growth. The following hygienic design criteria are required:

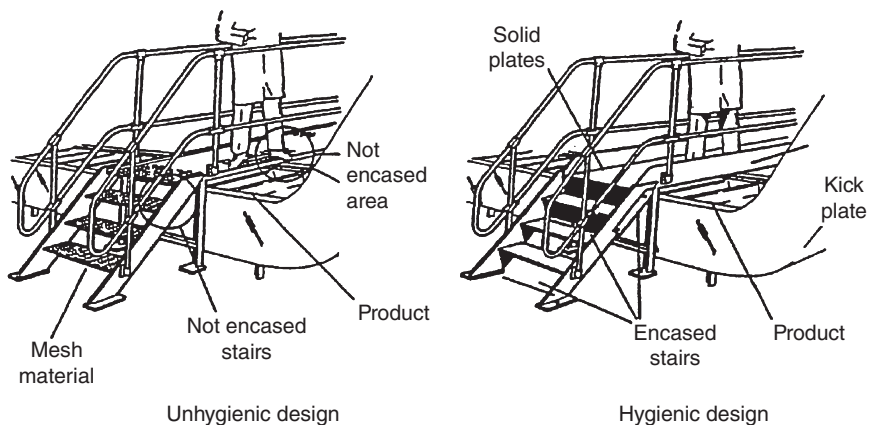
- Cables should be located wherever possible in designated utility/servicing areas.

- The wiring and cabling should be located in plastic or stainless steel pipes and prepared so that dust and moisture cannot enter the pipes, thus preventing the possible risk of creating contamination conditions.
- If used, cable trays should be of grid design and be accessible and easy to clean. Only one layer of cables is recommended and there must be space between the cables. Vertical cable trays are preferred.

Raised walkways or stairs over any exposed product should be avoided because dirt may be transferred from clothing or footwear onto product lines beneath. If personnel movement is required in these areas, the equipment should be constructed to be fully enclosed. Kick-plates should be designed as a one-piece construction. The decking should be constructed from solid plates containing a raised anti-slip surface. Risers of staircases must be encased. Steps should be constructed of the same anti-slip material as the deck. The use of expanded metal or mesh must be avoided to prevent soil being transferred into the product (Fig. 4.52 and Fig. 4.53).

Framework supporting equipment should preferably be constructed from hollow square- or round-section members. Open ends of such framework must be closed by welded ends or plastic caps. For the design of framework that will be exposed to continuous vibrations (e.g. drying towers) the use of open profile construction should be considered. Small cracks can arise from vibration, allowing penetration of moisture, soil and microorganisms in closed profiles.

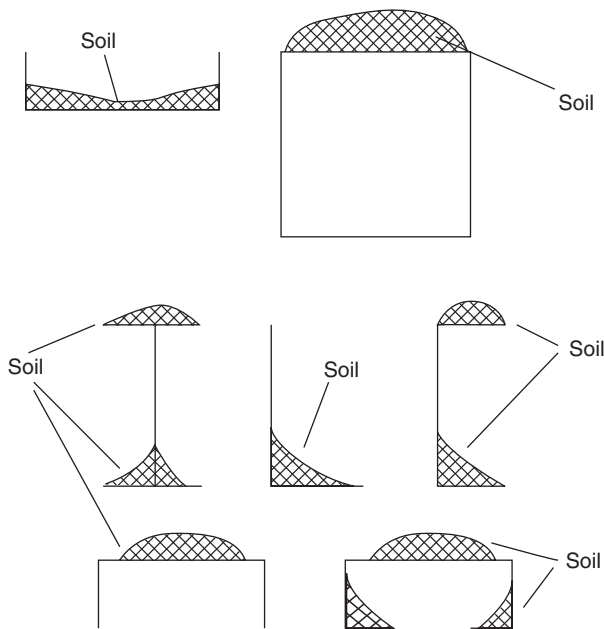
For vertical parts of frames most cross-sections can be used. The horizontal placing of framework is more problematic. Figure 4.54 shows how various kinds of open and closed design can attract soil. To avoid soil trapped on the horizontal surfaces of frames, open and closed cross-sections must be self-draining and easily cleanable. Horizontally mounted cross-sections and framework should be designed as shown in Fig. 4.55.



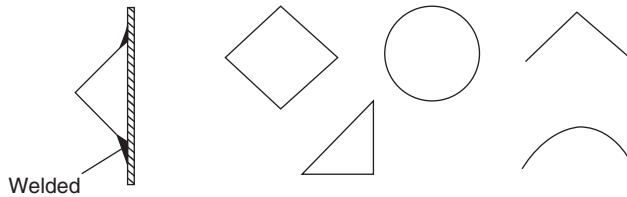
**Fig. 4.52** Hygienic and unhygienic design of walkways.



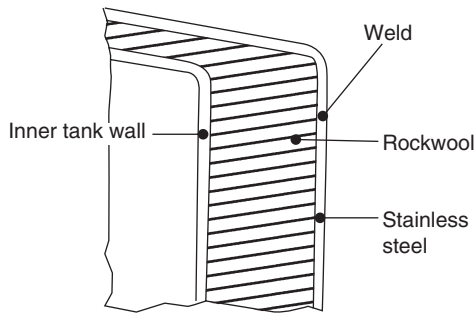
**Fig. 4.53** Hygienic design of steps for walkway (courtesy of Campen BRI).



**Fig. 4.54** Unhygienic design of supporting framework for equipment.



**Fig. 4.55** Hygienic design of supporting framework for equipment.



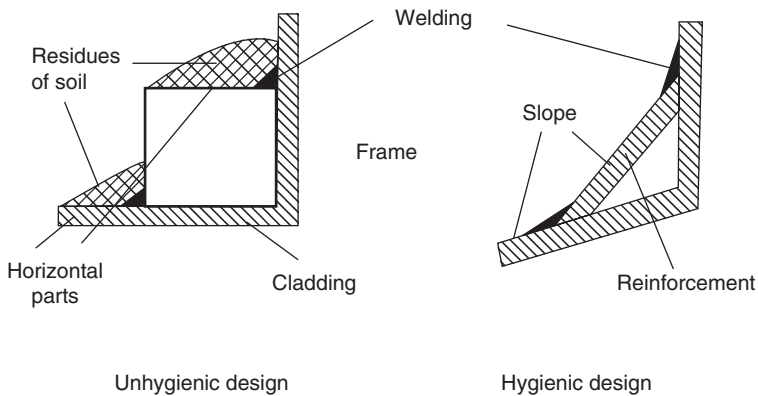
**Fig. 4.56** Hygienic design of insulation.

#### 4.17 Insulation and cladding

It is recommended to avoid use of insulation material wherever possible in order to prevent the possibility of microbial growth or dust build-up within the material (Hauser *et al.*, 2004b). If insulation is needed for process, safety and/or environmental reasons, air insulation is the first recommended option. Pipework can be insulated by evacuation of air in the shell of a double-walled pipe. This is a very effective way of meeting hygienic design criteria. If vacuum insulation is not possible, nonchloride-releasing insulation material should be used (such as appropriate grades of rockwool). The insulation material should be covered by a stainless steel outer tube, fully welded to prevent ingress of air, moisture or insects. Such ingress would promote corrosion between the walls, assisted by possible microbial growth. Ultimately, this will result in leaks, allowing microorganisms to contaminate the product. The same problem applies to the insulation of process vessels, which should be insulated in the same way, as shown in Fig. 4.56. Depending on the use of the tank, it may be necessary to provide a vent hole to prevent unacceptable pressures between inner and outer wall, e.g. during sterilisation.

Cladding of equipment must be smooth, continuous and without crevices to ensure that it is easily cleanable. Ledges, projections and pockets must be avoided because they retain soil. If unavoidable, horizontal ledges and projections should be sloped (Fig. 4.57). A minimum slope of 30° is required to avoid accumulation of dust and to facilitate inspection. Cladding must





**Fig. 4.57** Hygienic and unhygienic design of framework ledges.

be installed such that a minimum clearance of 30 cm is maintained between adjacent surfaces.

## 4.18 Conclusion

There is no reason to build process lines that are not of hygienic design. Understanding and using the information in this chapter will help designers and constructors to avoid mistakes and where there are still doubts, the references to literature, including many detailed guidelines should provide the required additional information. The contents of the chapter also provide information for the users of equipment and allow them to judge whether the equipment offered and installed meets the expected hygienic requirements.

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# 5

## Food processing equipment construction materials

**M. Lewan, Materials Engineering Research Laboratory Ltd, UK and  
E. Partington, Nickel Institute, UK**

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**Abstract:** This chapter discusses a range of processing equipment construction materials and their suitability in the food industry.

**Key words:** metals, plastics, composites, elastomers.

### 5.1 Introduction

The European Union Regulations (the 'Framework Directive' EC 1935/2004 of 1 August 2008, Article 3) require that 'food contact articles under normal or foreseeable conditions of use must not transfer their constituents to foods with which they are or are likely to be in contact in quantities which could endanger human health or bring about a deterioration in the organoleptic characteristics of food or an unacceptable change in its nature, substance or quality'. The Directive also requires that equipment manufacturers and the subsequent owners of food processing equipment and food contact materials maintain such records (usually by means of an appropriate batch numbering system) as are necessary to ensure that all food contact materials are fully traceable, at least one stage backward and one stage forward in the supply chain. For this section a range of materials and their suitability in the food industry is briefly discussed. Where appropriate an applications and corresponding testing scheme is shown in the form of a flow diagram.

Product contact materials must meet a number of requirements. They must be inert to the product under operating conditions, including variations in temperature and pressure, as well as to detergents and disinfectants under normal or reasonably anticipated conditions of use. They must be corrosion resistant, non-toxic, mechanically stable, smooth and cleanable,

and such that the surface finish is not adversely affected by the conditions of use. For practical, rather than legislative reasons, non-product-contact materials must also be mechanically stable, smoothly finished and easily cleanable.

Only materials which are demonstrably non-toxic in the proposed concentrations and intended conditions should be used. If such a selection cannot be based upon an unassailable and extensive history of non-toxicity in a relevant environment, appropriate testing must be carried out. Stainless steels such as grades AISI 304 and AISI 316 and their low-carbon (more easily welded) versions are fully acceptable for most applications. However, care must be taken when polymer and elastomer materials are used as they may contain leachable, potentially toxic, components. The same applies to the use of adhesives, lubricants and signal transfer liquids. In all cases the supplier must present evidence that the material is safe for use in contact with food.

Product contact surfaces should be smooth enough to be easily cleanable. A surface finish of  $R_a$  0.8  $\mu\text{m}$  or smoother is recommended for large product-contact areas. If this surface finish cannot be achieved for any reason, a modification of the cleaning regime – such as an increase in detergent time, detergent velocity or detergent temperature – may be necessary to ensure the required result. To achieve a sufficiently smooth surface, polishing or other surface treatment may be required, particularly after welding. Cold-rolled stainless steel sheet material, used for vessels and for piping, usually has an  $R_a$  value between 0.2 and 0.5  $\mu\text{m}$  and thus treatment is not needed, except at welds. The surfaces should also be free from imperfections such as pits, folds and crevices.

To retain the desired smoothness of the surface, materials must be resistant to the product under process conditions and withstand cleaning procedures during the intended lifetime of the material. Corrosion can be minimised by observing the concentrations, times and temperatures specified for process and cleaning operations, and by complete removal of residues (or neutralisation if any are left at non-product-contact surfaces of equipment). Many food products contain chloride and have a pH between 3 and 5; a very corrosive combination. The corrosion resistance of stainless steel derives from a thin but impervious and tenacious film of iron/chromium oxide (the 'passive layer'), which forms naturally on a clean stainless steel surface when exposed to a supply of oxygen such as from the air or oxygenated water. If this passive layer is damaged, mechanically or chemically, it will normally repair itself very quickly if it is exposed to oxygen again. If for any reason (such as a lack of oxygen) this self-repair mechanism cannot take place, corrosion localised to the damage may ensue and could ultimately cause component failure for a relatively slight metal wastage. The quality of the passive layer and the speed of its formation, whether after damage or not, can be enhanced by treatment with oxidising acids, such as nitric acid. This treatment is called 'chemical passivation' or,

more commonly (but not strictly accurately), just 'passivation' and is discussed in Section 5.2.1. For most food and beverage applications, however, it is not necessary.

Manufacturers need to be aware of other potential problems associated with particular processes. As an example, non-metallic surfaces used in dry materials handling can create electrostatic charges, which can cause surface adhesion by small particles of contaminating material. Electrostatic effects during dry materials handling in pneumatic conveying and other systems can be problematic. Such systems require particular care in the selection and use of materials.

## 5.2 Metals in food processing equipment

In practice, the choice of metals available for use for food processing equipment is very limited. While in certain parts of the industry alloys other than stainless steels are used, it is generally the austenitic stainless steels that are the materials of choice for the construction of processing plant and equipment. Their popularity stems from their general resistance to corrosion by food products and the recommended cleaning regimes, as well as from the ease with which they can be formed, machined, welded, cleaned and sterilised.

In the majority of environments likely to be encountered in a food processing plant, stainless steels will demonstrate good service lives but, like any other group of materials, it is important to select the most appropriate grade (type) for the intended conditions, bearing in mind both the food product and the disinfecting and cleaning agents. (If choosing a free-cutting stainless steel, it is important to ensure that the grade does not include lead or selenium.) A range of appropriate stainless steels for food contact uses are shown in Table 5.1.

The austenitic 18%Cr/10%Ni AISI 304 stainless steel is suitable for a very wide range of applications, particularly where there will be only low levels of halide ions (which, in the food process industry, are almost always the chlorides associated with salty foods) as these can lead to pitting corrosion and stress corrosion cracking. Where the environment contains higher levels of chlorides (0.015–0.05%) at moderate temperatures (<60°C), the molybdenum-containing 17%Cr/12%Ni/2.5%Mo AISI 316 may be advisable. Its higher corrosion resistance makes it suitable for equipment such as valves, pump castings, rotors and shafts, while its low-carbon version AISI 316L is recommended for pipework and vessels due to its enhanced weldability. Where hardness is required (such as for cutting blades or the wearing parts of pumps) one of the martensitic stainless steels such as AISI 420 or AISI 440C may be necessary. For very aggressive environments there are the super-austenitic stainless steels such as 254SMO, with their higher chromium, nickel, molybdenum, copper and nitrogen contents, which

**Table 5.1** Typical compositions of the alloys referred to in this section

Type	Designation	DIN	C	Cr	Ni	Mo	Ti
Austenitic SS	AISI 304	1.4301	<0.07	17.0–19.5	8.0–10.5		
Austenitic SS	AISI 304L	1.4307	<0.03	17.5–19.5	8.0–10.0		
Austenitic SS	AISI 316	1.4401	<0.07	16.5–18.5	10.0–13.0	2.0–2.5	
Austenitic SS	AISI 316L	1.4404	<0.03	16.5–18.5	10.0–13.0	2.0–2.5	
Super-austenitic SS	254SMO		<0.02	19.5–20.5	17.5–18.5	6.0–6.5	
Martensitic SS	AISI 420	1.4021	0.16–0.25	12.0–14.0			
Martensitic SS	AISI 440C	1.4125	0.95–1.20	16.0–18.0		0.4–0.8	
Duplex SS	2205	1.4462	<0.03	21.0–23.0	4.5–6.5	2.5–3.5	
Duplex SS	2304	1.4362	<0.03	22.0–24.0	3.5–5.5	0.1–0.6	0.6–1.2
	Incoloy 825		<0.05	19.5–23.5	38.0–46.0	2.5–3.5	
	Hastelloy C-276			15.5	57.0	16	

There may be small additions of elements such as nitrogen and copper. The balance element is iron.

enhance their corrosion resistance, and the duplex stainless steels such as 2205 and 2304 with their high strength and toughness and greater resistance to stress corrosion cracking. Alternatively, Incoloy 825, with its very high chromium and nickel content, or even titanium, may be appropriate. However, it must be taken into account that each material will offer its own combination of corrosion resistance, hardness, formability, machinability, weldability – and cost. In practice, the first choice of the international suppliers of food processing equipment is frequently AISI 316.

However, equipment design can contribute significantly to a stainless steel's corrosion performance. The four most common forms of corrosion are localised pitting, crevice corrosion, deposit attack and stress corrosion cracking, although given the appropriate conditions, corrosion fatigue is another possible failure mode. Avoidance of crevices and minimisation of stresses (particularly cyclic) can extend the life of components significantly.

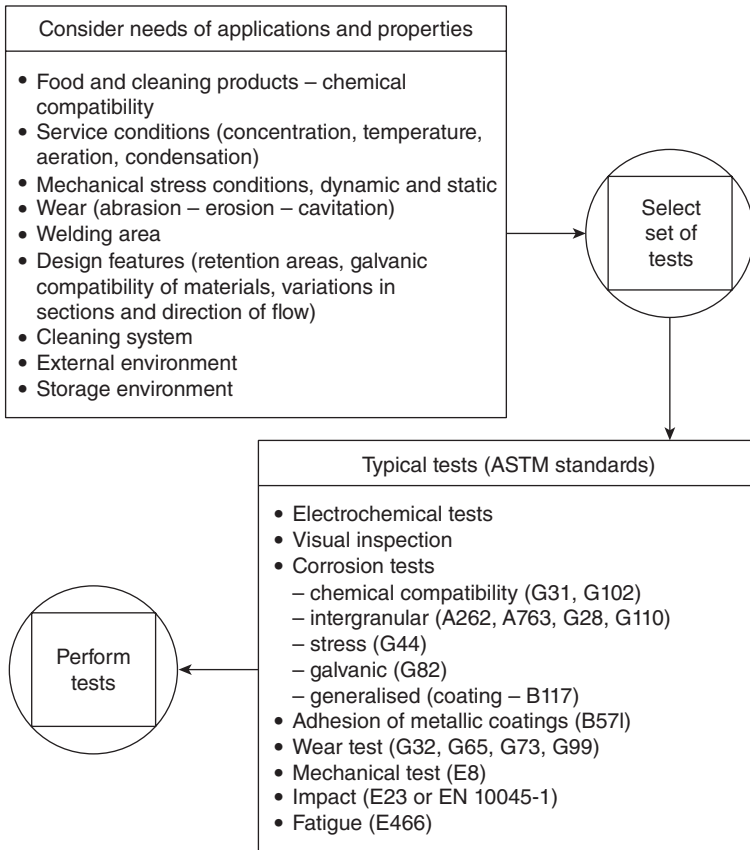
Aluminium is not sufficiently corrosion resistant and should generally be avoided for most moist or liquid food contact applications. If nickel- or chromium-plated equipment is used, the plating must be manufactured reliably and its integrity checked. It must be ascertained that under conditions of use the plating cannot flake or otherwise contaminate the product and that it is resistant to corrosion from food products, cleaning and disinfecting agents. Chemically plated materials should be preferred over electroplating because of higher durability and more compact and dense surface layers.

Hygienic dry materials handling is best conducted with product contact surfaces of stainless steel. Aluminium and aluminium alloys (coated and non-coated) may also be used as dry material contact surfaces where only dry cleaning is applied. Carbon steel can be considered as a contact surface only in components involving dry processing and dry cleaning operations.

It is inadvisable to bring into contact dissimilar metals by bolting together components made from, say, aluminium and stainless steel or two different steels, if they will then both be in contact with a liquid (or moist food) which can act as an electrolyte. The difference between the individual corrosion resistances of the metals can lead to an electrical current flowing between them and through the liquid which, while small, can greatly accelerate the rate at which one of the metals is then attacked by any corrosive environment. All metals (and alloys) exhibit their own specific 'nobility', a measure of their potential for corrosion. If two are in intimate contact and under an electrolyte, the one with the lower nobility will be preferentially corroded – and at a rate which reflects the difference between their respective nobilities. Where such contact is unavoidable, however, connecting the two components to a common electrical earthing system may preclude galvanic corrosion.

The flow diagram (Fig. 5.1) considers a number of factors that need to be taken into account when deciding which metal would be most suitable for the required application, and then gives a list of tests that would have





**Fig. 5.1** Metallics flow chart of potential applications and their associated tests.

to be carried out. The actual tests that are associated with the code numbers are shown below.

- A262 Practice for detecting susceptibility to intergranular attack in austenitic stainless steels
- A763 Practice for detecting susceptibility to intergranular attack in ferritic stainless steels
- B117 Test method for salt spray (fog) testing
- B57I Adhesion of metallic coatings
- G28 Test method for detecting susceptibility to intergranular attack in wrought, nickel rich, chromium bearing alloys
- G31 Practice for laboratory immersion corrosion testing of metals
- G32 Test method for cavitation erosion using vibratory apparatus
- G36 Practice for evaluating stress corrosion cracking test in a boiling magnesium chloride solution

- G44 Practice for evaluating stress corrosion cracking resistance of metals and alloys by alternate immersion in 3.5% sodium chloride solution
- G65 Measuring abrasion using the dry sand/rubber wheel apparatus
- G73 Practice for liquid impingement erosion testing
- G82 Guide for development and use of a galvanic series for predicting galvanic corrosion performance
- G99 Test method for wear testing with a pin-on disk apparatus
- G102 Practice for calculation of corrosion rates related information from electrochemical measurements
- G110 Practice for evaluating intergranular corrosion resistance of heat treatable aluminium alloys by immersion in sodium chloride and hydrogen peroxide solution
- E8 Test methods for tension testing of metallic materials

### 5.2.1 Passivation of stainless steel

Stainless steel derives its corrosion resistance from a thin, durable layer of a complex oxide that forms spontaneously at the metal's surface and gives stainless steel its characteristic 'stainless' quality. This passive layer consists of a mix of iron, chromium and sometimes molybdenum oxides. It forms instantaneously in air or oxygenated water if the stainless steel is clean. This natural process is called 'passivation'.

Chemical passivation is an important surface treatment that can enhance the corrosion-resistant performance of stainless steels used for product contact surfaces. Chemical passivation processes enhance the chromium fraction (and therefore corrosion resistance) in the passive film.

Chemical passivation treatments are not designed to remove contaminants or defects such as the heat tint resultant from welding, embedded iron particles, heat-treatment scale and other surface defects produced during fabrication. Elimination of these defects requires removal of between 25 and 40 µm of the substrate metal by pickling of the surface with a nitric-hydrofluoric acid mixture. Electrocleaning and electropolishing techniques are also useful alternatives to pickling.

The chemical passivation process consists of:

- mechanical cleaning;
- degreasing;
- inspection;
- passivation (immersion or spraying);
- rinsing.

Cleaning and degreasing remove surface contaminants whilst the inspection stage checks that these stages have been successfully completed prior to chemical passivation. The part to be passivated is then immersed or sprayed (depending on the size of the piece) in, for instance, a nitric acid

(HNO<sub>3</sub>) solution. There are a number of solution variations (containing a combination of other oxidising acids) appropriate for all grades of stainless steel, in various heat treatment conditions and surface finishes. The use of an oxidising acid (such as nitric acid) for chemical passivation has two purposes: firstly, the acid dissolves any high-carbon steel particles which may adhere to the surface; secondly, it ensures a uniform, clean surface that results in the consistent formation of the passive chromium oxide film. Detailed information on passivation can be found in EHEDG Guideline Document 18 *Chemical Treatment of Stainless Steel Surfaces* ([www.ehedg.org](http://www.ehedg.org)).

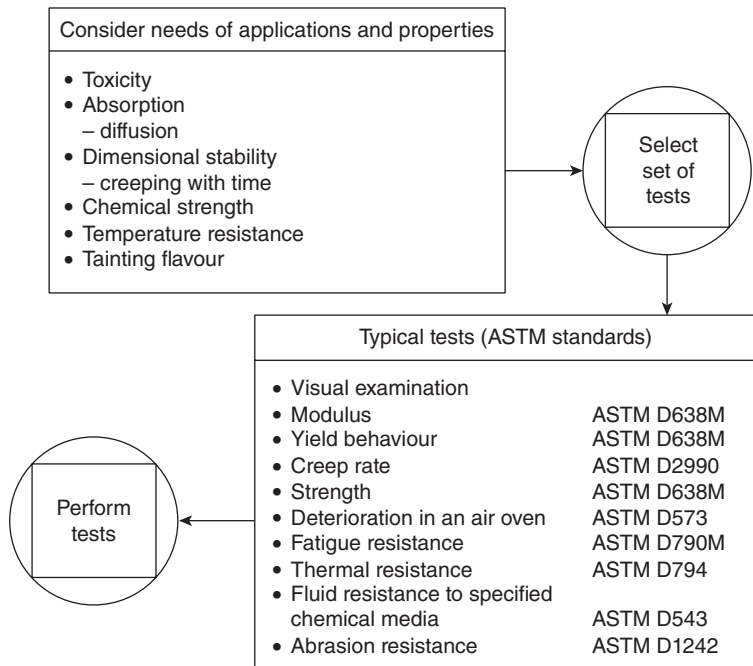
### 5.3 Plastics, composites and elastomers

#### 5.3.1 Plastics

Plastics are used in many areas, such as storage holders, hoses, pistons, conveyor systems, chains, moulds and polymethyl methacrylate sight glass. Plastic materials are often used to protect tools and implements from metal-to-metal contact (e.g. for shear edges of cutters), as guides and covers, or for hoses because of their plasticity and corrosion resistance. It must be noted that some plastics are porous and can absorb product constituents and harbour microorganisms. Poor initial selection has resulted in many failures of plastic components. Hence, the type of polymer must be approved for the application it is to be used for. There is such a wide range of different types of plastics with various properties that specific guidance, as given for stainless steel, is not possible. There is no standardisation available and it is dangerous to standardise. Thus only key points have been listed in Fig. 5.2.

Only certain materials are approved for food contact applications and the supplier should be asked for details of the approved certification, and to demonstrate that the correct protocol has been followed to get approval in appropriate circumstances. The transfer of 'tainted' plastic results in the quality of the food being diminished. This occurs when food diffuses into the plastic and then subsequently there is leakage out of the plastic and back into 'later' food. Thus, diffusion rates and mechanical property changes must be determined. It should be noted that some cleaning detergents attack plastics, so it is essential that the correct agent is chosen for this purpose.

Plastics may degrade with time in certain chemical environments and the application of mechanical stress can accelerate this process and lead to environmental stress cracking (ESC). Combinations of effects, e.g. strain and temperature, occur in practice, so must also be considered. Accelerated tests can be performed that will enable plastics selection to be made in a more informed way. The problem with accelerated tests is that the method needs to be verified, i.e. extrapolation of the predictions and validity for



**Fig. 5.2** Plastics flow chart of potential applications and their associated tests.

the application. Injudicious choice of ageing temperatures also needs to be avoided. Specific plastics should be qualified for specific service conditions and expected lifetime. Currently fibre-reinforced plastics (FRP) and glass-reinforced plastics (GRP) are used for special cases, mainly at the front end of the process, e.g: conveyor belts and the storage of raw materials, etc.

The following plastics are easy to clean and are used in hygienic design:

- polypropylene (PP);
- polyvinylchloride (PVC) unplasticised;
- acetal copolymer;
- polycarbonate (PC);
- high-density polyethylene (PE).

Care should be taken if using polytetrafluoroethylene (PTFE) because it can be porous and then be difficult to clean. PTFE is not resilient enough to provide a permanently tight seal and is unsuitable for equipment intended for aseptic processing. Any exposed reinforcements (such as glass or carbon fibres and glass beads) in plastics should not come into contact with the product, unless the bond between reinforcement and plastic is such that penetration of product is not possible.

### 5.3.2 Composites

The main problem with woven composites is that they are susceptible to delamination, and for GRPs this can lead to the break-up of the glass fibre. However, special cases do exist, e.g. lined composite pipes. The use of carbon fibre could also help solve the problem. Typical tests that might need to be considered when choosing the most appropriate composite and the corresponding ASTM standards are shown below:

- Longitudinal tensile/compression modulus and strength (ASTM D3039, D3410)
- Transverse tensile/compression modulus and strength (ASTM D3039, D3410)
- In-plane/Interlaminar shear modulus and strength (ASTM D3518, ASTM D2344)
- Interlaminar fracture (ASTM D5528).

### 5.3.3 Elastomers

Rubber is one of the most widely used components for materials and equipment in the food industry. Rubber represents a family of materials whose main characteristic is high elasticity (resilience), i.e. the ability to return to the original shape once removed from the source of the stress. For this reason, rubber is considered the best material for objects such as gaskets, caps and hoses. A rubber compound is composed of a number of ingredients, e.g. elastomers, mineral fillers, plasticisers, activators, antioxidants, accelerants and vulcanising agents. The intrinsic properties of the rubber compound mainly originate from the elastomer, which is composed of long repetitive molecular chains of various origins, e.g. NR (natural rubber), EPDM (ethylene-propylene-terpolymers), CIIR (chlorobutyl-isoprene-isobutylene-rubber), NBR (acrylonitrile-butadiene-rubber) and SBR (styrene butadiene rubber).

Currently, compiling a list of suitable materials for a job is difficult for the following reasons:

- There are no standards for compounding between suppliers – thus precise compound formulations, mixing cycles and curing are required.
- All the conditions the material encounters, not just one specific condition, must be taken into account. These include not only such items as temperature range, ozone, UV and fat compatibility, but also what the material is attached to, e.g. end fittings, and how it is treated, e.g. bent once and left in that position or subjected to continuous bending.

To complicate the issue, there is a very wide range of elastomer types and for each one a large number of elastomer compounds that may be mixed by the supplier. Each of these may have different mechanical and chemical properties.

Accelerated tests can be performed that will enable elastomer selection to be made in a more informed way. However, there are limits to the knowledge available to interpret accelerated life tests. Thus, specific elastomer compounds should be assessed for specific service conditions and expected lifetime.

When considering fluid compatibility both mass uptake and leaching of ingredients by diffusion should be considered. Mass uptake curves should be obtained towards equilibrium and single-point fluid exposure tests should not be relied upon. For seals, the stress relaxation rate will reduce the sealing force and this may be enhanced by temperature cycles or by fluid contact during service even if there is no chemical effect.

Most suppliers' literature gives information on individual conditions, e.g. effect of stress, effect of temperature, etc. However, in reality the material will be affected by a combination of stresses and temperatures and this is not usually taken into account. It is important to know that high temperature combined with high stress can lead to premature failure. The scheme shown in Fig. 5.3 describes the general method for choosing the correct rubber for food products. Test results will decide whether a certain kind of rubber is or is not in accordance with the required standards, which themselves can change from time to time.

Many different types of elastomers are used in the food industry for seals, gaskets and joint rings. The recommended choices are:

- EPDM – though EPDM is *not* oil and fat resistant;
- nitrile rubber;
- NBR;
- silicon rubber;
- fluoroelastomer (Viton).

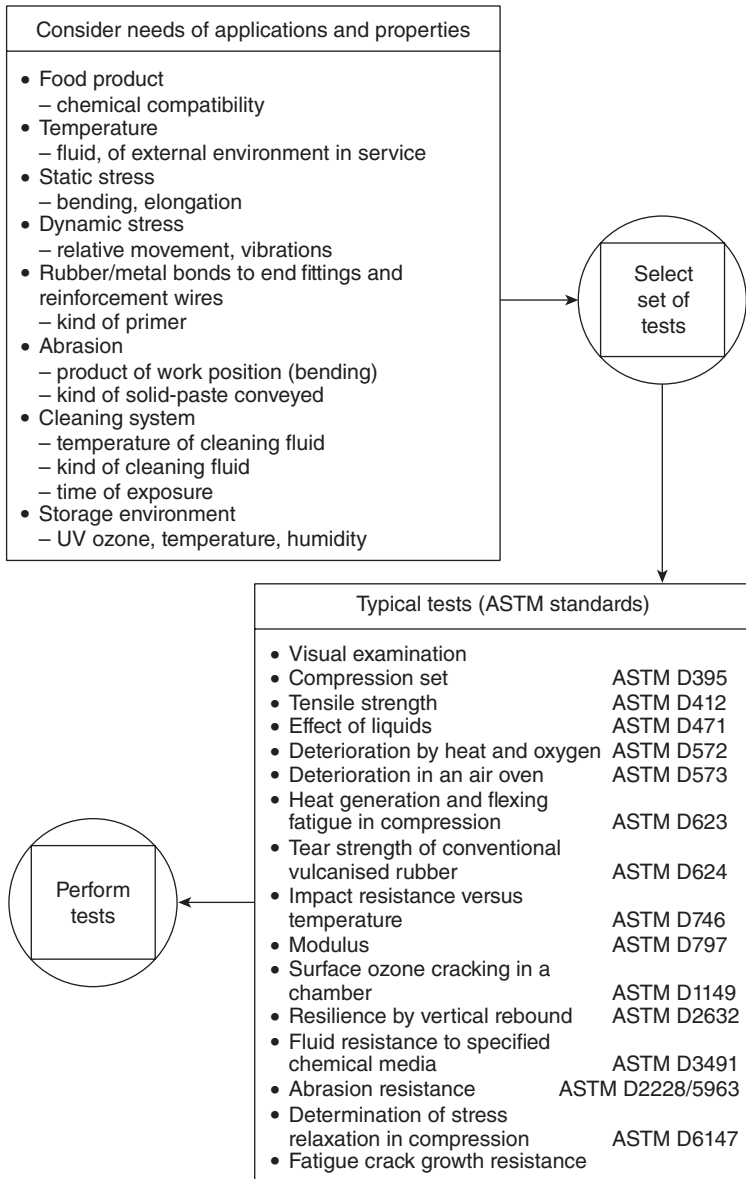
The last two are appropriate for high-temperature applications (up to 180°C).

As with plastics, any reinforcement should not be allowed to contact product, unless the bond between the elastomer and the reinforcement is such that penetration of product is not possible. Excessive compression will cause damage to rubber components and may cause the elastomer to extrude into the product zone, adversely affecting cleanability. Therefore, where an elastomer is used as a seal between solid surfaces, the compression of the elastomer must be controlled (also taking into account thermal expansion during pasteurisation or sterilisation of product or equipment).

All replacement parts should be certified as appropriate for food use.

Certification can come from:

- elastomers – relevant EU and USA legislation;
- plastics – relevant EU and USA legislation;
- metals – EU (council of Europe) and USA legislation.



**Fig. 5.3** Elastomers flow chart of potential applications and their associated tests.

## 5.4 Other materials

Ceramics are often used only for highly specialised applications such as active mechanical seal elements on rotating equipment. The use of glass is discouraged due to problems of detection in the plant should a breakage occur, but if glass has to be used, it has to be protected with a plastic coating. (Glass is commonly used as jars and containers, but not in product manufacture.)

Adhesives used for keeping gaskets in place must be non-toxic. They should always comply with the recommendations of the supplier of the equipment for which those gaskets are used. Adhesives can cause localised corrosion of stainless steel if not used according to the supplier's specification. All bonds must be continuous and mechanically sound so that the adhesive does not separate from the base materials to which it is bonded. Adhesives must be resistant to products and process conditions such as temperature.

Insulation equipment must be installed in such a way that the insulation cannot be wetted by ingress of water from the outside environment (e.g. hosing down, or condensation on cold surfaces). Ingress of water may lead to a build-up of chloride on stainless steel surfaces, resulting in stress corrosion cracking or pitting corrosion. Chloride attack can also take place from chloride release by improperly chosen insulating materials. Ingress of water will also encourage microbial growth and increase the risk of microbial contamination. Liquids used for signal transfer may come into contact with the process fluids if a membrane leaks. Food-grade qualities of silicone oil or glycerine should be used for this purpose.

Wood is appropriate only in a limited number of cases, for example when it plays a favourable role for relative humidity regulation and/or microbiology ecology (cheese ripening, the production of wine, vinegar, etc.) or when its mechanical properties cannot be obtained with other available materials (e.g. butchers' blocks). Wooden surfaces must be cleaned effectively and disinfected because they can retain microorganisms which can subsequently grow in the presence of product nutrients. Splinters can result in foreign body contamination.



## 6

# Verification and certification of hygienic design in food processing

**J. Hofmann, European Hygienic Engineering & Design Group, Germany  
and T. R. Rugh, 3-A Sanitary Standards, USA**

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**Abstract:** Verification and certification of hygienic design are essential to provide all authorities with proper assurance that food processing equipment and systems will comply with relevant legislation. Today, the European Hygienic Engineering & Design Group (EHEDG) oversees a comprehensive programme in Europe to certify equipment that complies with hygienic design criteria. In the United States, 3-A Sanitary Standards, Inc. (3-A SSI) administers the 3-A Symbol authorisation program to show conformance of equipment to the design criteria of 3-A Sanitary Standards.

**Key words:** European Hygienic Engineering & Design Group, 3-A Sanitary Standards, test methods, cleanability, bacterial tightness, EHEDG certification, 3-A Symbol authorisation, third party verification.

## 6.1 Introduction

The effectiveness of the hygienic design of food processing equipment will sometimes need to be verified. Reasons for verification include the following:

- to demonstrate compliance with relevant hygiene legislation such as the European Union (EU) Machinery Directive (2006/42/EC);
- as part of a quality assurance scheme used by an equipment manufacturer to check the quality of its design and manufacturing processes;
- to meet the requirements of a customer contract and to demonstrate the cleanability;
- to ascertain that a new or modified design does not conflict with hygienic design criteria.

The nature of verification will depend on a number of factors, including:

- The complexity of the equipment;
- Whether it is equipment used in 'open' processing (for example a conveyor belt) or in 'closed' processing (such as a pumps and valves in pipe lines);
- The required hygiene status of the production line. There are differences in the design requirements whether it is used before the main decontamination stage in a production process, or to handle decontaminated food before it is sealed within its packaging (e.g. aseptic filling).

Verification methods for open equipment not handling decontaminated product can be relatively simple. They may involve the following:

- Examination of two- or three-dimensional plans to check compliance with food principles of hygienic design.
- Examination of the equipment itself, including dismantling it if required (accessibility is important).
- Checking materials used to manufacture the equipment are allowed to be used in food contact.

Verification of this kind may be sufficient for many types of open equipment to comply with the EU Machinery Directive (2006/42/EC) and are allowed to have the 'CE' mark. However, for more complex equipment, particularly closed equipment handling decontaminated product, more elaborate tests may be required. There are three main types of in-place tests, also used for certification of equipment:

- Cleanability, i.e. the suitability to easily clean equipment in comparison to a reference pipe and to prevent areas (e.g. crevices) where product residues, soil and microorganisms can accumulate.
- Sterilisability, i.e. to test whether equipment is free of any microorganism, including bacterial spores, after a standard heat treatment.
- Bacterial tightness, i.e. the ability of the equipment to prevent the ingress of microorganisms.

## 6.2 Testing methods

### 6.2.1 Testing the assessment of in-place cleanability

Food factories need regular cleaning to avoid products becoming contaminated with soil, product residues and microorganisms. The cleaning process should be as short as possible to have more time available for food production. But it must be very effective not to create more hygienic hazards for food contamination. Whether surfaces of equipment can be cleaned does not only depend on the soiling, the chemicals and the time but also on the design of the equipment. To improve the process it is

important to have easily cleanable equipment. Crevices and dead ends in the process line will not be influenced by the chemicals within a short time and therefore these areas must be avoided.

Testing the assessment of in-place cleanability is one possibility to show that the design of the equipment is easy to clean. The test procedure is based on a Unilever R&D Vlaardingen adaptation (Lelieveld, 1985) of a methodology described by Galesloot *et al.*, (1967) and is designed to indicate areas of poor hygienic design in equipment where product or microorganisms are protected from the action of the cleaning process.

The method is based on a comparison, in the laboratory, of the cleanability of a test item with that of a straight piece of pipe, or reference pipe. This is soiled and cleaned in the same way as the surfaces under investigation. The degree of cleanliness is based on the removal of a soil containing bacteria and is assessed by evaluating the growth of bacteria remaining after cleaning. The level of cleaning is designed, using a mild detergent, to leave some soil in a reference pipe of known surface roughness to facilitate cleanability comparisons between the test item and the reference pipe.

Methods for testing the cleanability of food processing equipment involve various stages including (Lelieveld, 1985):

- ensuring that the equipment is initially clean;
- soiling with organic soil mixed with indicator microorganisms;
- undertaking cleaning;
- measuring residual microorganisms still present on the surface after cleaning.

EHEDG has published in document no. 2 a test method to assess the in-place cleanability of small equipment used in pipe lines (EHEDG, 2011a). The soiling is done with soured milk including bacteria spores of *Geobacillus stearothermophilus* var. *calidolactis*. This soil has a low surface tension and is able to wet all areas of the test pieces. After drying the soil onto the surface a hard layer of soured milk with the adhered spores is left. The cleaning is done in a standard procedure:

- Rinse with cold water (10–20°C) for 1 minute.
- Circulation of a 1.0% (w/v) mild caustic detergent solution for 10 minutes at 63°C.
- A final rinse with cold water (10–20°C) for 1 minute.

For all pipe sizes, cleaning solution is to be circulated at a mean velocity of flow of 1.5 m/s within the reference pipe which has the same diameter as the test equipment.

After cleaning the test section is removed from the cleaning rig and filled with nutrient, a special agar mixed with a pH-sensitive indicator for this microorganism strain. It is cooled down to solidify the agar. The next step is the incubation at a temperature of 58°C, the optimum temperature for the *Geobacillus* and a temperature where no other acid-producing

microorganisms are growing any more. Finally the residual soil is detected. The agar is prepared out of the reference pipe and the test piece. If microorganisms are left on the surface after cleaning, they will germinate in contact with the nutrient and will produce acid. This will turn the purple colour of the agar to yellow. The detection of residual soil is shown in the discoloration of the agar. The test is repeated up to five times to get a reproducible result. Three results are possible for the test item:

- Presence of milk residues: if everything went right, poor hygienic design is detected. These areas could not be cleaned at all. No further tests have to be performed and a design change is necessary.
- Presence of yellow zones and/or colonies: if the yellow zones are randomly distributed and related to the degree of cleaning undertaken, a comparison to the reference pipe is done. Presence of retained soil in the same area of the test item on two occasions is indicative of areas that are difficult to clean, and hence areas in which improvements in hygienic design should be considered.
- No yellow zones/colonies: the test item can be described as particularly cleanable.

Only if randomly distributed yellow zones or no yellow zones are detected in the test item, can the equipment be classified as easily cleanable. This test can only be used for single pieces of equipment such as valves and pumps. The total size of the equipment is limited by the volume of the incubator and the limit in pipe diameter is related to the test rig to achieve the flow velocity of 1.5 m/s.

Specialised and independent laboratories are offering the test method to the industry. A list of EHEDG accepted laboratories is available on the EHEDG website in the of Testing & Certification (<http://www.ehedg.org/?nr=17&lang=en>).

### **6.2.2 Testing the aseptic properties of equipment**

Cleanability is the prerequisite for all kind of equipment used in food production. Some applications have higher demands for the hygiene status of the production line and the environment. If the food is sterilised on its own and afterwards it still has contact with machinery, this equipment must be designed in a way that does not re-contaminate the food. Therefore steam sterilisability and bacteria tightness are two additional requirements to food processing equipment which can be tested.

#### *Steam sterilisability*

The EHEDG has established a method to test in-line steam sterilisability of equipment (EHEDG, 2011b). The method is designed to indicate whether an item of equipment can be freed internally from viable microorganisms by in-line steam sterilisation.

Prior to testing, the equipment to be investigated is dismantled and thoroughly cleaned and sterilised in the autoclave. All the inner surfaces of the dismantled equipment are wetted with a diluted spore suspension (*Bacillus subtilis* spores at a concentration of  $5 \times 10^7/\text{ml}$ ). After drying the equipment will be reassembled and mounted in the test rig for a standard steam sterilisation (saturated steam at  $121^\circ\text{C}$  for 30 min). A nutrient medium is introduced into the test equipment by means of a peristaltic pump. To avoid anaerobic conditions the broth is circulated for 2 hours every day. The test circuit is kept at ambient temperature (approximately  $20\text{--}25^\circ\text{C}$ ) for at least 5 days.

If the broth remains clear after 5 days the equipment is classified as in-line steam sterilisable. If the broth becomes turbid, a sample is taken and examined microscopically for the presence of *Bacillus subtilis*.

### *Bacteria tightness*

The bacterial tightness of equipment can be tested by another standard EHEDG method (EHEDG, 2011c) following the EHEDG sterilisation test (EHEDG, 2011b). To test bacterial tightness, *Serratia marcescens* is used. This is a small, strongly motile microorganism able to penetrate through small holes and crevices which are difficult to test by other physical methods. The indicator microorganism is cultivated in sterile trypticase soy broth (TSB). TSB is also pumped into the equipment to provide a growth medium for any indicator microorganisms able to penetrate the equipment.

If not preceded by a sterilisability test, the equipment is dismantled, cleaned and then sterilised. It is then reassembled under aseptic conditions and the TSB introduced into the equipment. A freshly prepared culture containing at least  $10^9$  bacteria/ml is diluted in sterile TSB and spread evenly over all critical and suspected parts of the equipment. Syringes may be required to ensure that the more inaccessible areas are properly covered. All areas where leakage may occur are treated twice a day for at least 3 days. Where applicable, the equipment is operated 10 times after each treatment. To obtain sufficient mixing and ensure rapid detection of microbial growth the TSB broth in the equipment is circulated for 2 hours every day. The equipment is kept at ambient temperature (approx  $20\text{--}25^\circ\text{C}$ ) during the soiling procedure.

After the soiling procedure the system is kept at ambient temperature (approximately  $20\text{--}25^\circ\text{C}$ ) for 5 more days. The TSB broth is circulated for 2 hours every day at the same flow rate used during the soiling procedure. If the broth remains clear after this period, the equipment is classified as bacteria tight. If the broth becomes turbid, a sample is taken and examined for the presence of *Serratia marcescens*. If *Serratia marcescens* is present in the system, the equipment has failed the test and is, therefore, not bacteria tight and hence not suitable for aseptic use. Tests should be conducted a minimum of three times. If varying results are obtained, a thorough examination of the test procedures and equipment should be conducted. If

no faults are discovered, it can be concluded that the equipment is bacteria tight.

### 6.3 Particular tests for cleanability

This section covers the following tests:

- beta-carotene residues test;
- *Pseudomonas fragi* test;
- *Bacillus thuringiensis* test;
- 'Campden soil' method;
- 'buttermilk' test;
- ATP-swab test.

#### 6.3.1 EHEDG $\beta$ -carotene residues test for closed equipment

In this method a test item is filled with a commercially available soft margarine, containing 80% fat with a viscosity of less than 60 mPa s at room temperature, and pressurised to 5 bar. After cleaning, the test item is removed from the test rig and dismantled. All product contact surfaces of the test item can then be examined for the presence of residual soil by visual inspection and by swabbing the surface with a cotton wool tipped swab. The relative amount of residual soil is recorded on a relative number (RN) scale from 0 to 4 where 0 represents no visible yellow soil and 4 indicates soil being highly visible. One difference from the EHEDG microbiological method is that instead of a bacterial spore, a colorant ( $\beta$ -carotene) is used as soil residue indicator (EHEDG, 1997).

This method is easier to apply and gives results faster, but is less sensitive than the microbiological method. The method is also cheap and suitable as a means of reducing the number of the more expensive microbiological tests required during the development of new food processing equipment. The detection of  $\beta$ -carotene in margarine soils is dependent on visual observation, since automated colour recognition systems have been found to be less sensitive than the human eye. In addition, techniques based on absorbance spectrophotometry after extraction of the  $\beta$ -carotene into hexane have also proved less sensitive. As test results are thus recorded on an arbitrary (RN) scale, statistical analysis of repeatability studies by the RN scale is difficult. Visual comparison of results does, however, suggest that similar results can be obtained. Further work is required on the quantification of the level of  $\beta$ -carotene remaining in margarine on the surfaces of large pieces of equipment after cleaning. If no suitable automated system can be found, appropriate colour charts to enhance the RN scoring system could be considered to allow reproducible results between partners.

### 6.3.2 *P. fragi* test method for exposed surfaces

In this method, overnight cultures of *P. fragi* are resuspended in phosphate buffer and sprayed onto test surfaces using a small compressed air-based sprayer (Merck) with spraying in a zigzag pattern to give even coverage. The surfaces or equipment are allowed to dry for 15 minutes and then sprayed with growth media (0.1% bacteriological peptone, 0.07% yeast extract) prior to cleaning. After cleaning, surfaces are swabbed, the swabs processed traditionally or the swab re-suspension fluid assessed by total viable counts (TVP), adenosine triphosphate (ATP) or direct epifluorescent microscopy (DEM)/direct epifluorescent filter (DEF) as appropriate.

Those using *P. fragi* as a test organism have found it to be easy to use and results are repeatable. The measurement of *P. fragi* by TVC also has the largest range of detection in that cleaning can remove >5 log orders of the organism attached to surfaces. This range allows even small differences in the cleanability of surfaces to be detected, though such small differences may not be relevant practically. Further work, however, needs to concentrate on the method's reproducibility, i.e. how to standardise its methodology and interpretation between partners, as the principles of the method (choice of organism, method of soiling, cleaning variables and detection methods) currently vary among individual users. This method is currently used only in laboratories. In the future it may be possible to use edible micro-organisms, such as lactic acid bacteria, which would make the method acceptable for use in factories.

### 6.3.3 *B. thuringiensis* test method for exposed surfaces

In this method spores of *B. thuringiensis* are suspended in saline and sprayed onto surfaces with sweeping movements using a compressed air 'artist's brush' type paint sprayer or by filling the item of equipment with the spore suspension. Immediately after cleaning, surfaces are covered with molten nutrient agar containing 2,3,5-triphenyltetrazoliumchloride (TTC). The agar is incubated on the surface for a variable time period (up to 5 h) at 30°C and then removed from the surface and incubated overnight. TTC salts, which are water soluble in the oxidised state, are reduced to water-insoluble formazans by cellular respiration. When growing using this TTC solid medium, colonies appear red and small, offering an easier visualisation of the contaminated areas.

The detection of *B. thuringiensis* by TTC is limited by the ability to differentiate colonies on an agar surface. This probably covers a range of 1–100 colonies/cm<sup>2</sup>, above which colonies become indistinguishable (i.e. 2 log orders). This range is, however, sufficient to determine cleanability differences either by means of colony counts or by visual assessment. Methods using spores such as *B. thuringiensis* offer greater repeatability and reproducibility than vegetative bacterial-based tests, as spores have

high resistance to heat and chemicals as well as strong adhesive properties. They are less susceptible, therefore, to viability loss within the soiling and cleaning process. Difficulties arise, however, particularly for open surfaces, with the detection of spores if an agar overlay technique is used on large pieces of equipment, because it is impractical to cover them totally with agar and it may be difficult to cover only areas of the equipment identified as likely to be unhygienic. What is not known at this stage of development of the TTC methods is the ability of the agar to fully wet the surface and thus come in contact with all surface-bound spores and subsequently what proportion of spores are removed by the agar and are thus enumerated. The ability of the agar to enter into surface irregularities, e.g. crevices, and remove any spores present will clearly influence the sensitivity of the technique, though results to date have shown the method to be among the most sensitive of the five currently developed.

#### **6.3.4 'Campden soil' method for exposed surfaces**

In this method, a soil is prepared containing 'Coldflo' modified starch, whole milk powder and vegetable oil and spiked with calcium carbonate (final concentration 1.25M). This 'Campden soil' is then diluted 1:2 for spraying to excess onto equipment surfaces using, for example, a Merck TLC sprayer. After cleaning, surfaces are swabbed by sponges which are re-suspended in nitric acid. Diluted samples are aspirated into a Perkin Elmer 3300 atomic absorption spectrophotometer using an air/acetylene flame at 422.7 nm and results calculated as mg calcium/cm<sup>2</sup>.

This technique has proved very easy to use and is repeatable. Its detection is dependent, however, on access to atomic absorption spectroscopy which imposes a cost limitation to its widespread use. Alternative calcium detection methods are available and it may be possible for cheaper analyses to be undertaken. The simplicity, safety and repeatability of the calcium technique makes it particularly suitable for routine use outside the laboratory, especially in areas in which microbiological testing would be impossible, and it is certainly recommended for future study. The difference between cleaned and control surfaces as measured by calcium is approximately 1 log order. This range makes an assessment of the cleanability very difficult but is sufficient to detect areas of poor cleanability at a gross scale within individual test items.

#### **6.3.5 The 'buttermilk' test for filling machines**

This test has been assessed by the EHEDG and is appended to the EHEDG guidelines on the evaluation of packing machines (EHEDG, 2000). The objective of the test is to assess the interior cleanability cleaning-in-place (CIP) of filling machines. The machine is soiled with buttermilk containing a fluorescent dye. After cleaning, the product contact parts of the filling



machine are inspected for any residual fluorescence with ultraviolet light. The residues are then confirmed by an ATP test. In addition, a selected number of 'critical' parts are tested for ATP. This test is mainly intended for investigating the hygienic design of filling machines, but can in principle be used also to evaluate and document the effect of an existing cleaning programme, optimising cleaning programmes or comparing various cleaning agents. This test, however, may only be done at the location of the equipment manufacturer, using the required safety precautions. The fluorescent dye is not safe and should not be used in any food environment. For the same reason, it must be ascertained beyond any doubt that there are no residues left when the equipment is shipped to the user.

### **6.3.6 ATP-swab test**

This method was developed to have an easy to perform test available for the machinery supplier to test their equipment for in-place cleanability (Balley, 2000). The EHEDG in-place cleanability test is quite complicated and microbiological knowledge is necessary. The machinery builder often has the possibility to test the equipment with water or detergent, but has no microbiological lab available.

The test procedure is similar to the EHEDG test method. The equipment is thoroughly cleaned and sterilised. The soil is made of potato starch, whey protein and bakery yeast, which is the ATP source for residual detection. All product contact surfaces are soiled and the equipment is pressurised during soiling. After drying the soil the test piece is cleaned by a standard cleaning procedure according the EHEDG test method. Here only caustic with 1% is used instead of the EHEDG special detergent. The final step is the detection of residues on the surfaces. For this ATP swabs are used. Areas which are expected to be not easy cleanable will be swabbed and analysed. If the relative light unit (RLU) is higher than 1000, an area of poor hygienic design is detected. If the value is less than 500 RLU, easy cleanability can be classified. If the value is between 500 and 1000 RLU, it must be checked if there is a hygienic design problem or if this spot will vary within the repeated cleaning tests.

This method is not that sensitive like the EHEDG cleanability test but areas of poor hygienic design can be detected. Crevices at joints for examples will result in extremely varying values of RLU. This is an indication that soil can be trapped and the equipment is not easy to clean.

## **6.4 Future trends**

The official EHEDG in-place cleanability test method and also the test methods presented in Section 6.3 have their limits in applying to all kinds of equipment used in the food processing industry. All methods have in

common that they can be used for relatively small and individual components. Sometimes dismantling is necessary to get access to the relevant areas for the assessment of cleanability. On the other hand, the EN standard 1672-2 regulates that the cleanability of all kinds of equipment in food contact should be tested and validated. Therefore additional test methods are necessary to fill this gap and to give the designers of the equipment the guarantee that they fulfil the hygienic design criteria.

Developing new test methods is not that easy. Most of the published test methods validate a cleaning process and do not assess the cleanability. For this a standard cleaning procedure is necessary and the cleaning result must be compared with a reference piece. Small pieces of equipment can be handled in the lab, but if bigger machines should be tested, they are often installed in the food factory, ready to use. In this case, a soil with microorganisms is undesired or not allowed. The advantage of microorganisms is that a small amount of residues could be detected by progeny. Mineral substances used as tracer often have a quite high detection level and are therefore not good enough to detect poor hygienic design areas. An additional problem is the complexity of several machines used in open processes. A conveyor or a filling machine have hundreds of hygienic design relevant areas. To minimise the effort in the assessment, the test method must be easy, cheap and quick to perform. These are the challenges for all groups dealing with new test methods.

EHEDG's subgroup 'Test Methods' is developing new test methods in this field. After intense test series and gaining wide experience with these methods, they will be standardised between the EHEDG authorised testing institutes and subsequently integrated within the testing scheme for certification.

#### **6.4.1 Equipment for open processes**

Food production has to adapt to the modified demands of consumers and the retail market. In the past only food which was not sensitive against microbiological contamination was produced in open processes where the production environment has influence on the product quality. Nowadays highly sensitive products like sliced meat and sausages or ready to eat salad are also produced in open processes. Therefore the demand for easily cleanable and hygienically designed equipment and machines comes from the food manufacturer. To assess cleanability new test methods must be developed.

Machines used in open processes like a conveyor are often manually cleaned. The cleaning result depends on the personnel doing this job. To assess cleanability, standard procedures are needed for reproducibility. If this is taken into account new cleaning procedures have to be invented for these kinds of machines. Accessibility is mostly the biggest problem to clean these machines. Even if the design is in accordance with the hygienic

design requirements, these surfaces will not be clean if they cannot be reached. The consequence for the test method is that the first step is to check accessibility. This can be done by a simple spray shadow test or a wetting test according 3A. The second step would be the verification of hygienic design with a different method.

Developing a test method seems to be easy. Take a soil, contaminate the surface, clean the equipment and detect the residual. The challenge of a test method for the assessment of cleanability is to benchmark the cleaning effort. A comparison to a reference piece is needed, otherwise only the efficiency of the cleaning procedure is assessed. The aim of hygienic design is to ensure the surface can be cleaned in an easy way and to avoid any areas where soil can accumulate longer (although it may be possible to clean areas of poor hygienic design). Producing a hygienic design is complex and ambitious. Using a fluorescent dye like riboflavin as a soil, the cleaning mechanism is one solution. As long as the cleaning fluid passes over the surface, a constant mass transfer will render the fluorescent dye soluble. If the soil is in a crevice, cleaning fluid will enter this area by diffusion and will make the soil soluble. This is time consuming for complex machines with a lot of difficult areas. When using a soil with particles as tracer substances, the adhesion forces of these particles to the surfaces are relevant. They will not become soluble by diffusion out of a crevice. But as long as these particles are inorganic the residual number on the surface can be quite small. This is again a challenge when choosing an appropriate detection method.

#### **6.4.2 Large equipment (tanks and other machines)**

Quite similar to the issue explained above is the assessment of tank-mounted equipment and larger items of closed or semi-open food equipment. The cleaning fluid must be able to reach all relevant surfaces; otherwise cleaning will have no effect. The design of the tank and the position and type of the spraying devices are essential for the cleaning effect. Due to the wide variety of the combinations it is a large expenditure to test all the possibilities. On the other hand, it is not possible to transfer a cleaning result from one tested arrangement to other designs. To reach the goal of easy cleanability the total number of spray nozzles should be at a minimum. The cleaning fluid volume and energy needed to provide the correct pressure at the nozzles should be taken into account. For this kind of equipment it is also necessary to invent a reference piece to assess and compare the cleanability.

### **6.5 Certification of equipment**

Long before the first legislation on the subject appeared, food processors started to negotiate with equipment manufacturers about the hygienic

design and cleanability of the equipment provided. In the USA this resulted in the foundation of the 3-A organisation as early as 1927. In most countries food processors are now legally responsible for the safety of their products. Manufacturers specify the quality of the raw materials purchased and carefully define the process conditions needed to obtain a safe product of the right quality. Manufacturers are also responsible for ensuring the equipment they use is of the right standard. This need has led to demands for ways of certifying the hygienic quality of products.

There are two organisations that provide a certification scheme for the hygienic design of equipment. The oldest is the 3-A Sanitary Standards Symbol Administrative Council in the USA. In the late 1990s the EHEDG initiated the development of a certification scheme in Europe. The objective is to certify equipment that complies with hygienic design criteria, specified and discussed in the EHEDG publication *Hygienic equipment design criteria* (EHEDG, 2004). The scheme has operated since 2001 and is executed on behalf of EHEDG by 'EHEDG Authorised Organisations'.

### **6.5.1 Certification of equipment according to the EHEDG**

The EHEDG certification scheme was launched in the year 2001 and was based on the assessment of equipment according the Hygienic equipment design criteria of EHEDG provided in document no. 8 (EHEDG, 2004). This document also describes the testing requirements for assessing the hygienic and aseptic characteristics of equipment. This scheme was mainly applied to closed equipment intended for CIP cleaning. However, additional demands from the industry necessitate the expansion of the certification possibilities. In 2009 the certification scheme was revised and was more clearly defined to include additional certification categories for equipment used in aseptic applications, in open processing and dry material handling equipment. Equipment certification according to the new scheme is authorised to display a specific EHEDG logo according to the certification class together with the month and year of certification. In connection with this expanded scheme a matrix was produced to define the certification classes applicable to specific categories of equipment and the intended cleaning procedure. This has the main effect on the design of the equipment. Possible certification classes are:

- Type EL class I: cleaned wet, CIP, used in open and closed processes, practical test for closed equipment available.
- Type EL class II: cleaned wet with dismantling, used in open and closed processes.
- Type EL Aseptic class I: cleaned wet, CIP, used in closed processes, practical test for sterilisability and bacteria tightness must be done.
- Type EL Aseptic class II: cleaned wet with dismantling, used in closed processes, practical test for sterilisability and bacteria tightness must be done.

- Type ED: cleaned dry, automatic or manual cleaning, used in open and closed processes.

Certification of all equipment must be carried out by an EHEDG authorised institute and is subject to contractual conditions. A list of all certified equipment is published on the EHEDG website.

The assessment procedure is conducted in a number of stages. Initially, a sectional arrangement drawing of the assembled equipment and detailed drawings of subassemblies and components are examined according to the hygienic equipment design criteria contained in document no. 8 (EHEDG, 2004) for the principal hygienic design criteria to be met. Any other EHEDG documents applicable to the specific equipment are also used for the design review including installation considerations. Unhygienic design features, such as crevices, dead spaces and sharp internal angles can be identified at this stage. The next stage is to ensure that the hygienic design criteria are met in practice. This examination can reveal areas of poor hygienic design that were not apparent on the two or three dimensional drawings, such as the positioning of seals and control of seal compression. Additionally, surfaces are examined to check that the finishes specified have been achieved and any welds have been performed correctly and are crevice free. If the equipment fully complies with all the hygienic design criteria applicable to the equipment and no static or dynamic seals are used within the design then cleanability testing is not always required and the equipment can be certified. Examples include simple pipe bends or sensors that fully comply with the materials of construction, welding procedures, surface finish and radius requirements of the hygienic design criteria and contain no crevices or dead spaces. Equipment that does not fully comply with the relevant hygienic design criteria for essential technical or functional reasons or equipment containing static and dynamic seals needs to be tested according to the testing scheme on cleanability. Testing is conducted according to the applicable test method (EHEDG, 2011a) and successful results are necessary in order to proceed with certification (Timperley, 2011).

This provided equipment manufacturer's assessment of the hygienic design of equipment and the EHEDG website contains a list of all certified equipment.

## **6.5.2 Qualification of equipment in the United States: 3-A symbol authorisation**

### *3-A Sanitary Standards*

During the 1920s, the need for more stringent and uniform standards for dairy processing equipment became evident as the US economy and consumers entered the modern industrial era. Representatives of three interest groups – processors, regulatory sanitarians and equipment fabricators – recognised the need to resolve conflicting jurisdictional

regulatory requirements and to establish commonly accepted design criteria for equipment used in the transport and processing of dairy products. This cooperative action led to the first standards for equipment used in the dairy industry. Unlike other types of standards, 3-A Sanitary Standards relate to the cleanability of dairy equipment. These standards became known as '3-A' standards for the three interest groups that forged a common commitment to improving equipment design and sanitation.

The associations representing these three stakeholder groups continued to cooperate over decades to develop standards for a wide range of virtually all major types of equipment used in the processing of fluid milk and dairy products. In 1944, the US Public Health Service offered full cooperation with the '3-A programme'. This marked the beginning of a programme to provide uniform equipment standards for the protection of public health.

Oversight of work was vested in a 3-A Steering Committee with representatives of the three interest groups. Over the decades of cooperation, each association group contributed voluntary support in the form of personnel time and materials to develop, coordinate, publish and promote 3-A Sanitary Standards. In addition to standards for individual types of equipment, the organisations developed a number of guidelines for processing systems, known as 3-A Accepted Practices. Today, 3-A SSI maintains 69 individual 3-A Sanitary Standards encompassing virtually all the major types of equipment involved in the processing and transport of fluid milk and dairy products and 10 3-A Accepted Practices.

These documents are especially significant in commerce because the criteria for sanitary design are referenced in the US regulatory requirements for equipment used in dairy processing operations. All equipment which fully complies with the criteria set forth in the applicable 3-A Sanitary Standards or 3-A Accepted Practice is accepted as meeting the requirements of the US Department of Agriculture (USDA) General Specifications for Approved Dairy Plants and Standards for Grades of Dairy Products as outlined in 7 CFR 58.101 through 58.938.

Likewise, 3-A sanitary design criteria are recognised in the Grade 'A' Pasteurized Milk Ordinance (PMO), published by the US Public Health Service, Food and Drug Administration. The PMO sets milk sanitation standards for interstate carriers and milk/milk products shipped in interstate commerce and is recognised by the Public Health Agencies, the milk industry, and many others as the national standard for milk sanitation. The PMO references state, 'equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance.'

#### *Formation of 3-A Sanitary Standards, Inc.*

During the early 2000 period, the principal stakeholder organisations recognised several driving forces in the need for a change in the scope and organisation of the '3-A program', specifically:

- to advance the regulatory goals of USDA, the Food and Drug Administration (FDA), regional and local agencies through a credible third party verification programme for food processing equipment and systems;
- to promote recognition and adoption of 3-A sanitary design criteria worldwide;
- to administer a modern, effective, and efficient consensus process to develop national standards;
- to advance the application of 3-A Sanitary Standards in the processing of all comestible products;
- to maintain a sound, progressive and respected organisation to serve the evolving interests of all stakeholders in sanitary equipment design and advance the goal of public health.

This led to the incorporation of 3-A Sanitary Standards, Inc. (3-A SSI) as an independent, non-profit corporation in late 2002. 3-A SSI officially began operations in January 2003. Representatives of the three interest groups became vested in the leadership of a new, independent nonprofit organisation with a dedicated, full-time professional staff. 3-A SSI is responsible for administration of the 3-A Symbol program, coordination of all consensus documents, education on sanitary design and other activities.

3-A SSI is governed by a Board of Directors with representatives from the member associations, including the American Dairy Products Institute (ADPI), the Food Processing Suppliers Association (FPSA), the International Association for Food Protection (IAFP), and the International Dairy Foods Association (IDFA). The leadership of 3-A SSI includes the FDA, the USDA, and the 3-A Steering Committee. The 3-A Sanitary Standards Symbol Administrative Council participated as a founding member of 3-A SSI. The Council was dissolved in 2007 and legal ownership of the 3-A Symbol was conveyed to 3-A SSI.

The mission and the goals of the new nonprofit organisation reflect many elements of the historic 3-A program, including the development of voluntary standards and accepted practices. The new 3-A SSI maintains many significant added responsibilities, including increased oversight of the 3-A Symbol used to identify equipment manufactured to 3-A Sanitary Standards. Under the direction of 3-A SSI, a new program was launched in 2003 to enhance the recognition of the 3-A Symbol with a new Third Party Verification (TPV) program.

#### *The 3-A Symbol: then and now*

In 1956, the first processing equipment was introduced bearing a registered mark, the 3-A Symbol. The 3-A Symbol was originally owned and controlled by a non-government authority called the 3-A Sanitary Standards Symbol Administrative Council, Inc. The mark was offered to fabricators on a voluntary basis. By display of the 3-A Symbol, processing equipment could



be shown to meet a given 3-A Sanitary Standard and all criteria for materials of construction, design, fabrication, cleanability and inspection. Until the formation of 3-A SSI, use and display of the 3-A Symbol was authorised by the Council based primarily on a declaration of conformance signed by a management representative of the licensee.

Today, 3-A SSI does not truly 'approve,' 'certify,' 'rate,' or 'endorse' the design, construction or use of equipment. 3-A SSI is responsible for granting the authorisation to use and display the 3-A Symbol in conjunction with the marketing of equipment and machinery that meets the requirements of published 3-A Sanitary Standards. The use and display of the 3-A Symbol is strictly voluntary and subject to specific conditions described in the 3-A SSI License Agreement for Use of the 3-A Symbol. Authorised 3-A Symbol holders must pay an annual licence fee set by 3-A SSI. A public listing of authorised 3-A Symbol holders is maintained on the 3-A SSI website.

With the creation of 3-A SSI, a new TPV inspection requirement was implemented as a condition for holding authorisation to use the 3-A Symbol. The TPV requirement applies to all equipment built to 3-A Sanitary Standards that is licensed to display the 3-A Symbol. A licensee must engage an inspection/verification professional accredited by 3-A SSI, a Certified Conformance Evaluator (CCE), to conduct an on-site evaluation of finished equipment and other product attributes to affirm the equipment conforms to the provisions of the applicable 3-A Sanitary Standard.

To earn accreditation as a CCE, an individual must:

- meet specific criteria for education and work experience;
- have high professional integrity;
- pass a comprehensive written exam;
- undergo special CCE orientation training programme.

Once accredited by 3-A SSI, a CCE must meet specific continuing education requirements set by 3-A SSI, including participation in periodic phone conferences, training and education offered in conjunction with the 3-A SSI Annual Meeting, or other optional outside presentations relating to sanitary equipment design. A list of the CCEs is maintained on the 3-A SSI website.

The TPV inspection is performed based on an agreement between the CCE and the 3-A Symbol applicant or licensee. All CCEs use a standard Third Party Verification Report for 3-A Symbol Authorisation and a copy of the appropriate 3-A Sanitary Standard for the inspection. In brief:

- the CCE reviews drawings, bills of material, material certificates, and compares to the requirements of the 3-A Sanitary Standard;
- the CCE inspects an actual sample of finished equipment – checks radii, surface finish, welds, etc;
- the CCE must visit the fabrication plant to verify an ongoing, effective quality assurance programme and to review other data, including



engineering drawings, instruction manuals, etc. A visit is required to the site of manufacture or final assembly of the equipment.

Following the TPV inspection, the CCE completes the final reports and creates four copies:

- One report goes to 3-A SSI as the original or authentic copy for the licensee.
- Two copies go to the fabricator or licensee; one is for the company's file and one is to be sent to 3-A SSI.
- One is reserved for the CCE's file.

Any deficiencies discovered in an inspection/verification must be corrected before the equipment can be authorised to display the 3-A Symbol. Equipment manufacturers that do not comply with the TPV inspection requirement will lose their right to display the 3-A Symbol on their products.

The TPV inspection report is valid for a period for five years. A new TPV inspection must be performed at any time the licensee introduces significant design changes or when there is a verified incident of non-conformance on the part of the licensee, known as a Report of Alleged Nonconformance or RAN. The RAN form is available on the 3-A SSI website and 3-A SSI urges any interested party to submit a completed RAN form for any product that may be out of conformance with a specific 3-A Sanitary Standard. The RAN represents one of the important ways for 3-A SSI to help monitor ongoing compliance with the 3-A Symbol programme.

The TPV programme is designed to enhance the integrity of the 3-A Symbol by affirming that equipment is fabricated in accordance to 3-A Sanitary Standards. The TPV inspection provides added assurance of hygienic equipment design and thereby benefits regulatory sanitarians, equipment fabricators, processors, and consumers.

3-A SSI has designated a TPV Coordinating Committee to oversee the TPV programme and to recommend programme improvements to the 3-A SSI Board of Directors. All provisions of the 3-A Symbol authorisation programme and the TPV inspection requirements are publicly available on the 3-A SSI web site at [www.3-a.org](http://www.3-a.org).

### **6.5.3 The 3-A Symbol and other marks**

3-A SSI maintains close working relationships with other organisations that are involved in the evaluation of equipment and the administration of licensed marks. The activities and services of other organisations differ from the 3-A Symbol programme.

#### *USDA Dairy accepted equipment*

The listing of equipment in the USDA Dairy Grading Branch Accepted Equipment List is entirely separate and distinct from 3-A Symbol

authorisation. It is USDA Dairy Grading Branch policy to fully support the established 3-A Sanitary Standards programmes and to encourage equipment manufacturers, distributors, and the dairy plant and users to participate fully in the development and application of the 3-A Sanitary Standards and 3-A Accepted Practices. This equipment listing is not intended to include all equipment which complies with established 3-A Sanitary Standards or 3-A Accepted Practices. There may be instances, however, when such equipment is included in this listing in order to provide clarification about its use within dairy plants surveyed and approved for USDA grading service. Equipment which is not covered by established 3-A Sanitary Standards or Accepted Practices will be reviewed by the Dairy Grading Branch utilising requirements of Section 58.128 of the USDA General Specifications and the USDA Guidelines for the Sanitary Design and Fabrication of Dairy Processing Equipment. When a manufacturer's advertising references USDA acceptance, the correct terminology is 'Model XXX has been reviewed and accepted by the Dairy Grading Branch, USDA for use in dairy plants surveyed and approved for USDA grading service.' USDA acceptance does not constitute authorisation to use the 3-A Symbol.

#### *NSF International*

As an independent, not-for-profit organisation, NSF offers programmes and services to augment and support the work of regulatory officials around the country, including standards development, product testing and certification, as well as onsite audits and inspections. In addition, NSF offers continuing education and training in many areas of environmental health, including air, water and food safety. 3-A SSI has worked with NSF as joint developers of three standards for meat and poultry equipment. The use of the 3-A Symbol is not authorised for equipment under these three standards.

## **6.6 Conclusion**

The programmes of EHEDG and 3-A SSI reflect slightly different approaches to the verification and certification or qualification of food processing equipment to hygienic design criteria. Both programmes embody a substantial breadth and in-depth knowledge of all aspects of equipment and systems design.

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## Control of airborne contamination in food processing

**K. L. Brown, formerly Campden BRI, UK and  
S. Wray, Filtration Engineering Ltd, UK**

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**Abstract:** The air is an important potential source of microorganisms, including pathogens. Microbial aerosols in high-risk food production environments can be controlled using the appropriate air filters combined with production practices that minimise aerosol generation within the high-risk area. Measures to control dust, temperature and humidity may also be required. ‘Plastic’ packaging can generate high electrostatic charge that can increase the rate of microbial contamination. There are several methods to disinfect air including disinfectant fogging, UV, ozone and hydrogen peroxide. The number of airborne microorganisms can be determined using a variety of air sampling methods. There are critical factors in the use of these methods including use of correction tables and sampler calibration. The relationship between airborne counts and different product contamination rates is described.

**Key words:** microbial aerosols, dust, air quality, air filtration, humidity control, electrostatic charge, air disinfection, air sampling methods and calibration, airborne counts, product contamination rates.

### 7.1 Introduction: why control of airborne contamination is important in food production

The air is an important potential source of microorganisms and pathogens, and the air in the majority of food processing areas, be it low or high risk, has to be controlled and meet a minimum standard (Wray, 2011). In addition, environmental air of a particular quality (temperature, humidity, dust and microbial content, and outside air make-up) may be required for the manufacture of specific products. For example, chilled food production areas are often run at a temperature of 10–12 °C in order to maintain the chill temperature of product prior to packaging. Once product is sealed inside a container, it is more difficult to chill the product if it is above the

required temperature. For high hygiene areas (e.g. high-care and high-risk areas), the aim of the air handling system is to supply suitably filtered air, at the correct temperature and humidity, and at a slight overpressure to prevent the ingress of air from external, uncontrolled sources (e.g. low-risk production and packing or from outside the factory). The Chilled Food Association (2006) defines high-care areas (HCA) and high-risk areas (HRA).

Control of airborne dust in cereal milling operations is important for worker health and to minimise the risk of explosions. Dry product areas may also require humidity control to prevent hygroscopic ingredients becoming spoilt. Dust can be generated from a variety of dry product and ingredient handling operations. The significance of the presence of dust may range from simple nuisance (requiring regular cleaning) to inhalation hazard or risk of explosion. Particle diameters less than  $10\mu\text{m}$  are of concern for respiratory damage to humans. Occupational asthma caused by flour dust is of concern in the baking industry (Tee, 1993). Flour dust is a respiratory sensitiser. The maximum exposure limit (MEL) is  $10\text{mg}/\text{m}^3$  (8 h time weighted average (TWA)) (EH40/2005). Dust explosions have caused serious industrial accidents in the food industry. Explosible food dusts include flour, custard powder, instant coffee, sugar, dried milk, potato powder and soup powder. Further information is available in the Health and Safety Executive publication HSG 103 (HSE, 2003) and on the HSE website, <http://www.hse.gov.uk>. The explosive properties of dispersed flour dust are described in *Chorleywood Digest*, issue 119 (Anon., 1992).

It is important to determine whether airborne contamination is a significant factor in the contamination of the product. Burfoot *et al.* (2007) demonstrated that poultry carcasses entering an evisceration room were so heavily contaminated that the airborne bacteria contributed less than 1% of the total numbers of bacteria on the poultry carcasses. The airborne route contributed to surface contamination in cattle slaughterhouses but other vectors were more important (Burfoot *et al.*, 2006) while in lamb slaughterhouses, surface contacts were also more important than airborne contamination.

Airborne contamination of product is thus a combination of the microbial load of the air, the time the product is exposed to the air (sedimentation from the air in still conditions) or as an interaction with the air if the air is used for, for example, cooling or fluming of the product.

### 7.1.1 Characteristics of microbial aerosols

Types of airborne contamination include dust, water droplets, skin particles and airborne microorganisms. Airborne microorganisms can be free-floating as in the case of bacterial or fungal spores, suspended in water droplets, or attached to dust or skin particles. The mistake is often made of assuming that the particle size of airborne microorganisms is the same as that of the

microorganisms themselves. This is not often the case. Frequently the particle size will be much larger; for example, a  $1\mu\text{m}$  diameter bacterium may be inside a  $15\text{--}25\mu\text{m}$  diameter water droplet. Skin particles according to Noble (1961) have a mean equivalent diameter of  $13.5\mu\text{m}$  and fewer than 30% of the particles carrying staphylococci were less than  $10\mu\text{m}$  in equivalent diameter. Clark and Cox (1973) calculated that of the order of  $7 \times 10^6$  skin scales per minute are liberated from the human body.

Microorganisms can be dispersed in airborne water droplets that are generated by cleaning operations. Holah *et al.* (1990) demonstrated the potential for spread of *Listeria* in food production areas by use of hoses and spray lances. Droplets containing microorganisms can also be dispersed from condensate on the cooling fins of evaporative chillers by the velocity of air going through the chiller. Large water droplets above  $15\text{--}20\mu\text{m}$  will not remain airborne for long, whereas smaller droplets will disperse readily. Some cleaning operations, e.g. boot washer brushes, also impart a ballistic force to droplets that can disperse quite large (1 mm) droplets 1 or 2 metres from source.

Burfoot (2005) summarised the results of a study into the relationship between airborne particle size and microbial contamination risk from different cleaning operations. While much of the airborne contamination from boot scrubbing and floor scrubbing fell close to the source, the most surprising result was that hand washing in a corner of the test area  $11.25\text{m} \times 10.25\text{m} \times 2.9\text{m}$  produced aerosols that were detected on settle plates throughout the test area (Burfoot and Brown, 2004). The test was done using 5 ml of spore suspension of *Bacillus subtilis* var *globigii* at a concentration of  $10^7/\text{ml}$  smeared onto the gloved hands of two people who then washed their hands for 60 seconds. Settle plates were exposed for 1 hour.

## 7.2 Sources of airborne contamination

### 7.2.1 Air from outside the controlled zone

The environmental air outside a factory will contain airborne microorganisms but the concentration may in fact be lower than inside the factory. Levels of airborne microorganisms outdoors depend very much on location, season, urbanisation and prevailing weather conditions. Levels may often be higher in rural locations, probably because of the much greater surface area of vegetation compared to city locations. In a study in Mexico City, Rosas *et al.* (1993) obtained airborne fungi counts ranging from 26 to  $603/\text{m}^3$  at three different locations. The arithmetic mean counts ranged from 96 to  $293/\text{m}^3$ . By comparison, Holah *et al.* (1995) reported a total viable count (TVC) mean of  $285/\text{m}^3$  and a fungal count of  $37/\text{m}^3$  outside 34 and 38 food factories respectively. These counts are low compared to those quoted by

Crook and Olenchock (1995) where counts of up to  $100/\text{m}^3$  TVC and  $1000/\text{m}^3$  fungi were found outdoors. The occurrence of yeasts and moulds in the food factory is reviewed by Voysey *et al.* (2007).

At a vegetable packing operation, Brown (2001) found a mean mould count outside the factory of  $81/\text{m}^3$  but inside the greenhouse supplying the factory the count was  $4923/\text{m}^3$  and in the packing hall it was  $1168/\text{m}^3$ . Clearly in this operation, the air in the greenhouse adjoining the packing hall was of more significance than the outside air quality. At a different factory equipped with a clean room, the TVC mean count was  $630/\text{m}^3$  outside the factory but only  $8/\text{m}^3$  inside the clean room.

### 7.2.2 Dust from milling and weighing operations

Milling operations, spray drying, weighing of powders and general handling of dried ingredients and products can create dust aerosols. Cleaning operations such as vacuuming can also generate airborne dust from the exhaust of the vacuum cleaner unless appropriate filters are fitted. In slow-moving air, large dust particles above  $15\text{--}20\mu\text{m}$  will quickly settle close to the source while smaller particles may remain airborne for some hours and travel long distances from the source. As air speed increases, even large particles will remain airborne and move considerable distances. An example of how far airborne dust particles can travel is demonstrated by the occasional deposition of sand from the Sahara desert in the UK.

Dutkiewicz *et al.* (2001) performed microbiological air sampling in two herb-processing factories located in eastern Poland. Air samples for determination of the levels of bacteria, fungi, dust and endotoxin were collected at 14 sites during cleaning, cutting, grinding, sieving, sorting and packing of 11 kinds of herbs.

It was found that processing of herbs was associated with very high levels of airborne bacteria, fungi, dust and endotoxin. The numbers of microorganisms (bacteria and fungi) in the air of herb processing factories ranged within  $40.6\text{--}627.4 \times 10^3 \text{ cfu}/\text{m}^3$ .

The concentrations of airborne dust ranged within  $3.2\text{--}946.0 \text{ mg}/\text{m}^3$ .

### 7.2.3 Water droplets from jacuzzi-style salad washing

Salad washing is sometimes done in jacuzzi-style systems. The breaking of air bubbles on the surface of the wash water is likely to generate aerosols of water droplets containing microorganisms (Sawyer *et al.*, 1993) and chlorine. One of the authors (Brown) once visited a salad-washing factory where the wash water contained  $70\text{--}100 \text{ ppm}$  chlorine. The aerosols generated from the wash tanks had entered the air handling system and corroded the aluminium cooling system fins in the main factory air handling system to such an extent that the fins had almost disappeared.

#### **7.2.4 Aerosols from cleaning operations (hoses, air lances, brushing, boot washing, hand washing, tray washing)**

It is vitally important that the potential for aerosols generated by cleaning operations to contaminate open product and food contact surfaces is understood (Burfoot, 2005; Burfoot and Brown, 2004). This is particularly important for high-risk operations where pathogens such as *Listeria* may be dispersed by lack of attention to cleaning operations (Holah *et al.*, 1990). *Listeria monocytogenes* has been shown to survive in aerosols for up to 210 min (Spurlock and Zottola, 1991). It is essential that cleaning equipment is itself cleaned regularly to prevent build-up of microorganisms inside the equipment, and use of highly dispersive techniques such as high-pressure hoses is severely restricted in high-risk areas and not allowed during production periods.

#### **7.2.5 People**

Spendlove and Fannin (1983) reviewed the sources of airborne microorganisms from people. Citing Buckland and Tyrell (1964), they reported that sneezing and blowing the nose were more than 1000 times more efficient than coughing in producing infectious aerosols from nasal secretions. Jennison (1942) showed with high-speed photography that up to 40000 droplets were expelled during a violent sneeze whereas a cough released only a few hundred droplets. Other researchers showed that the size of these droplets was in the range 0.5–12 µm with the majority being in the range 1–2 µm. Spendlove and Fannin (1983), citing May and Pomeroy (1973), reported that men are more profuse disseminators of bacterial aerosols than women: fully clothed men released 1008 cfu/min on average, whereas women released 75 cfu/min on average.

Brown *et al.* (2002) investigated the factors affecting the release of airborne particles and bacteria from people. A clean environment, 3.42 m<sup>3</sup> body box was constructed for the work. Typically, personnel released between 10<sup>5</sup> and 10<sup>6</sup> particles/m<sup>3</sup> into the body box in 5 min. Bacterial release was lower, typically 10<sup>2</sup> to 10<sup>3</sup> cfu/m<sup>3</sup>. High particle counts did not always mean a correspondingly high airborne bacterial count. Particle size analyses showed that most of the particles released were smaller than 5 µm but the larger particles (over 10 µm) were more likely to land onto settle plates. Airborne particles released from personnel could still be detected 2 hours after the person had left the body box, showing that, once airborne, particles released from personnel could pose a risk for a long time.

Various clothing styles were evaluated for their ability to control particle and microbial release. Cleanroom styles were better at preventing particle and bacterial release than typical factory coats. Release of particles and bacteria from bare or covered arms with tight cuffs was similar and less than from covered arms with loose cuffs. Mobcaps were marginally better than hairnets and a close-fitting hood was better than all other designs.



'Bouffant'-style hats appeared to act as bellows when patted. Contact plates applied to the forehead and head hair picked up higher counts from people with little or no hair than from people with long hair. In simulated factory trials, with four people in a room ( $43\text{ m}^3$ ) the mean numbers of bacteria landing on settle plates (90 mm diameter) in 5 min were 2.2–4.4 per plate, while presumptive *Staphylococcus* counts were between 0.7 and 1.4 per plate. Near to the people, the highest TVC and presumptive *Staphylococcus* counts were 7 and 3 per plate respectively in 5 min.

Brown and Holah (2006) produced guidelines for prevention of hair contamination of food that show the many different styles of head covering used by the food industry.

### 7.3 Dust control

Dust control should be viewed separately from general environmental air quality control. The filter systems used for dust control are quite different from those used for environmental air filtration. Dust control in the food industry serves five main purposes:

- To protect operators from inhaling fine particles, e.g. from milling operations.
- To prevent the spread of dust in processing areas which may lead to cross-contamination.
- To prevent accumulations of dust which could provide food for rodents and insects.
- To prevent environmental pollution.
- To minimise the risk of fire and explosion.

It is important to choose the correct dust control system for each application. Examples of different types of filtration and wet scrubber types of dust control are given in Tables 7.1 and 7.2. This is a specialist area and specialist advice should be sought.

### 7.4 Control of environmental air quality

A typical environmental air handling system (Brown, 2005) is shown in Fig. 7.1. This figure also shows the standardised terminology used by ventilation engineers. Not all systems will have all the components shown in Fig. 7.1 because installations tend to be tailor-made for individual sites. It is usual to recirculate a proportion of the air for energy-saving reasons. Outside air make-up is required to provide 'fresh' air for operatives to breathe and to replace air lost by transfer to other parts of the factory through doorways and conveyor hatches. Process air is shown as a separate supply and this is provided by a separate air compressor. Process air may be used simply to

**Table 7.1** Dust control systems

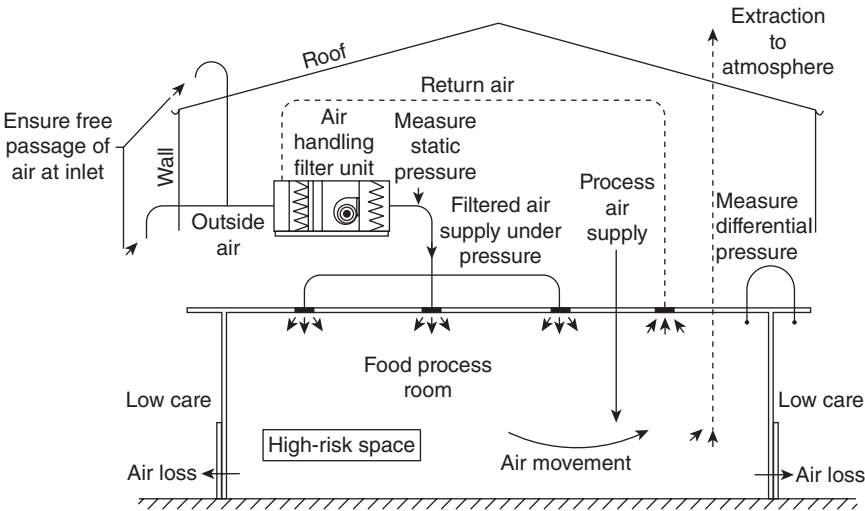
Filter type	Application	Comments
<b>Dry cyclones</b>	Pre-collector of large quantities of dust from conveying air	Not usually suitable as final filters. Efficiency rarely exceeds 80–90% for particles of 10 µm. Not generally used in the food industry
<b>Dry fabric filters (bag filters)</b>		
1. Static	Low dust load applications with intermittent use	Maintenance plan required on a set time basis
2. Mechanically shaken	Light to medium dust burden, intermittent use applications	Alternative bag styles available; take care in selecting correct filter for purpose
3. Reverse jet	Heavy continuous dust burden at constant pressure drop	Select correct bag filter for purpose. Membrane coated filter media achieve higher efficiency than conventional needle felt material
<b>Rigid element filters</b>		
1. Cartridge	Low-cost, high-efficiency filter	Over life of cartridge, pressure drop will rise steadily and this governs element change frequency
2. Rigid plastic element	High-efficiency, low failure	Not suitable for high temperatures or solvent atmospheres
<b>Secondary filters</b>	To prevent release of dust should failure occur in primary filter	
<b>Electrostatic precipitators</b>	Not used as product collectors. Main application for pollution control of fine particles in large exhaust systems	

operate pneumatic equipment or as headspace air in tanks or air to convey product. It is important that this air is of good microbiological quality if the controlled space is also being supplied with air that is filtered to a high standard and especially if it is in product contact.

A typical air handling system is shown in Fig. 7.2. Again not all components will be present in all installations. The fresh air and recirculated air mix together in a mixing box and then pass through the first or pre-filter.

**Table 7.2** Wet scrubber dust control systems

Filter type	Comments
Venturi	Most efficient of wet collectors. Efficiency increases with pressure drop across throat
Wet cyclonic separators	Low pressure drop, low-efficiency collector used mainly as mist eliminator to follow a more efficient wet collector
Induced spray or S-curtain	Medium-efficiency collector that relies on induced spray caused by negative pressure exerted by exhaust fan. Efficiency typically 80–90% by mass of input dust burden

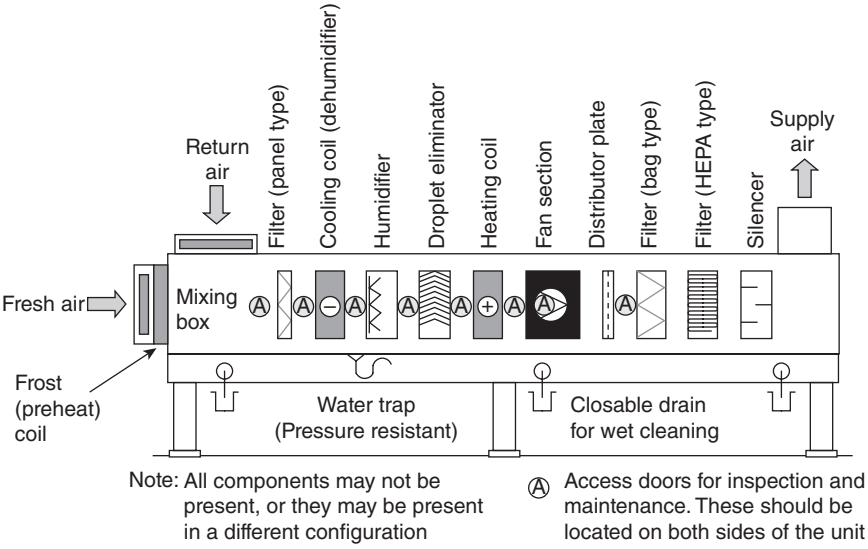


**Fig. 7.1** Schematic diagram of air movement route.

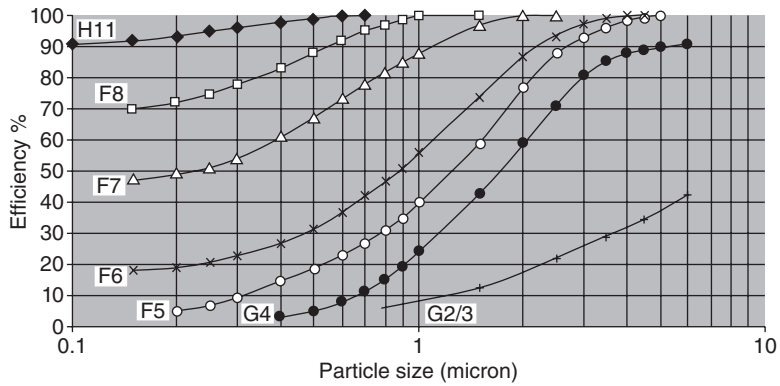
This first filter will be of a coarse grade and will protect the secondary and final filters from large dust particles and also help to protect the fan and motor from dust. The heating, cooling and humidification sections will be tailored to the customer's requirements. Cooling coils will require condensate drains that are designed to withstand the pressure inside the air handling unit. For design of water traps readers are referred to Brown (2005).

**7.4.1 Filtration**

Environmental air filters can be supplied in a range of efficiencies as shown in Table 7.3. A high-efficiency filter system will have a set of coarse, secondary and final filters. Choice of filter requirements depends on the air quality required into the controlled space. It should be appreciated that the environmental filter will provide clean air into the controlled space but will



**Fig. 7.2** Schematic diagram of typical configuration of an air handling unit.



**Fig. 7.3** Guide to particle removal efficiencies of different environmental filter grades when new (efficiency increases as filters become blocked with use).

not prevent generation of aerosols from cleaning and production operations within the area. Control of air quality needs to take into account practices within the controlled space and is not simply a question of installing a particular filter grade.

A common misconception is that a filter can be specified by simply stating the particle size that is required to be removed (e.g. 'A 2µm filter is required'). Reference to Fig. 7.3 (N.B. guidance only) will show that all filter grades from G2 to H11 will remove 2µm particles but with different

**Table 7.3** Environmental air filter reference chart based on EN779 for coarse and fine filters and BS EN 1822:2009 for EPA/HEPA/ULPA filters

Filter type	Arrestance or efficiency value (%)	Application
<b>EN779 coarse filters</b>		
G1	65	Used as pre-filters and (G4-F7) for some GMP low-risk food areas, e.g. fresh salad, raw meat, fish and fresh vegetables
G2	65–80	
G3	80–90	
G4	≥90	
<b>EN779 secondary or fine filters</b>		
F5	40–60	For general food processing areas (up to F7) and some high-care use (F7–F9) with risk assessment, e.g. pizzas, cheeses, pickles, prepared salads, baked pies
F6	60–80	
F7	80–90	
F8	90–95	
F9	≥95	
<b>EN1822: 2009 Efficient Particulate Air (EPA) filters</b>		
E10	≥85	For high-risk food process applications, e.g. recipe dishes, cooked sliced meats
E11	≥95	
E12	≥99.5	
<b>EN1822: 2009 High Efficiency Particulate Air (HEPA) filters</b>		
H13	≥99.95	For high-risk food applications where very clean air might be required, e.g. cooked sliced meats
H14	≥99.995	
<b>EN1822: 2009 Ultra Low Penetration Air (ULPA) filters</b>		
U15	≥99.9995	Mainly for laboratory work and mini environments
U16	≥99.99995	
U17	≥99.999995	

Note that this table is a guide only and specific product risk assessment needs to be done to determine the appropriate level of air quality required.

BS EN 1822: 2009 High efficiency air filters (EPA, HEPA and ULPA)

Part 1: Classification, performance testing, marking.

Part 2: Aerosol production, measuring equipment, particle counting statistics.

Part 3: Testing flat sheet filter media.

Part 4: Determining leakage of filter elements (scan method).

Part 5: Determining the efficiency of filter elements.

efficiencies. The same holds true for any other particle size. Filter efficiency also increases through the filter life cycle as the filter gradually becomes blocked. The choice of filter grade should therefore be made on the basis of the overall air quality required to be supplied to the controlled space. For a general good manufacturing practice (GMP) area, filter grades F5–F6 may be quite satisfactory; for low care, F7 should be adequate. ‘High-care’ areas would require filtration to F7–F9, whereas ‘high-risk’ areas would require E10 to E11 (H10–H11) (Wray, 2011). Again, it is emphasised that cleaning and production practices should mirror the air quality required.

### 7.4.2 Control of air movement

Filtered air is supplied to the controlled space usually through grilles or textile air 'socks'. Grille design, location and orientation have a significant effect on the direction and speed of air movement in the room. Textile 'sock' systems provide a more diffuse and gentler air movement. Air displacement systems are also available where air is supplied at low level and is extracted at ceiling level. Older installations simply provide clean air into the controlled space, air movement within the space being uncontrolled. The problem with these installations is that airborne contamination can be picked up and spread randomly throughout the controlled space.

A better approach is to control the air movement and air quality close to the open product. This is more likely to be successful in providing clean air consistently to the zone of risk close to the open product. Various methods are available for achieving local control, including unidirectional air flow, open troughs, semi-closed and totally enclosed tunnel systems (Burfoot *et al.*, 2000). For this experimental work, open conveyors were fitted with chilled filtered air supplies along each side and challenged with aerosols of spores of *B. subtilis* var. *globigii* at a concentration of approximately  $10^6$  per  $\text{m}^3$ . Settle plates were located alongside and on the conveyor and exposed for 55 min. The average colony count on the settle plates alongside the conveyor was around 500 whereas within the protected zone along the conveyor it varied from 0 to 35. The airborne challenge level was much higher than would be expected in a typical food factory but was set at  $10^6/\text{m}^3$  to give countable numbers of colonies within the protected zone. In a food factory airborne contamination of open product on conveyors could be reduced to insignificant levels using this principle.

### 7.4.3 Temperature and humidity control (including dew point, condensation and fog production in the air of process areas)

Many high-care and high-risk production areas are chilled to maintain a low product temperature during the production process. This is necessary because it is not usually practical or economic to chill the food once it is wrapped and stacked on pallets. In the UK, the Food Standards Agency (2007) specify a maximum temperature of  $8^\circ\text{C}$  for foods that may support the growth of harmful bacteria or formation of toxins.

(Note: On 1 January 2006 the Food Safety (Temperature Control) Regulations 1995 were revoked. Schedule 4 of the Food Hygiene Regulations 2006 implemented by separate but similar legislation in England, Wales, Scotland and Northern Ireland remade the majority of the requirements from the 1995 regulations. However, regulation 10 (the general requirement) and 11 (cooling of foods) are now contained within EC Regulation 852/2004, Annex II, Chapter IX, part 5 and 6 respectively.)

However, the Health and Safety Executive also specify a reasonable working temperature of at least  $16^\circ\text{C}$ , or  $13^\circ\text{C}$  where work involves serious

physical effort. There is therefore an apparent conflict of temperature requirements, one for food safety and the other for operator comfort. There are ways of addressing this issue as described in Brown (2000) where guidance is given on the legislation, product temperature control and risk assessment, design of air handling systems and clothing requirements for operatives.

Humidity problems in the food industry are usually caused by too much water in the air rather than too little; cheese maturation is an exception where humidity levels may need to be over 95%. It is very important to understand the relationship between humidity levels in the air, temperature, dew point and condensation using psychometric charts (which are readily downloadable from the Internet). As air temperature rises, it can hold more moisture, but if the air is then cooled or exposed to a cold surface, condensation may occur. This could then allow microbial growth, corrosion or other moisture-related problems such as absorption of water by dry ingredients. The most common method of dehumidifying air is to pass it through a cooling coil; the water then condenses and is drained away (Brown, 2005). The cooled dry air can then be warmed up to the desired temperature thus reducing the relative humidity. The cleaning and disinfection of cooling coils must be included as part of the overall air handling system hygiene programme.

Here are four examples of problems arising from lack of control over humidity as seen by Brown in food production areas. In the first example, warm, humid air from a cooking area was entering a chilled area through a conveyor opening. The warm air rose above the chilled air but then cooled below its dew point. The result was a dense mist upwards from waist height obscuring visibility.

In the second example, a freezer tunnel had been installed in a chilled humid production room. The much colder air from the tunnel flowed across the room at floor level, cooling the moist chilled air. This created a thick fog from the waist down.

In the third example, chilled air was introduced into a production room through a ceiling plenum and a perforated stainless steel ceiling. The ceiling became much colder than the room and the moist air in the room below condensed on the stainless steel. The result was continuous rain of condensation from the ceiling onto the product and operatives.

In the final example, warm humid air was extracted from the production area through a ceiling grille. This was connected to metal ducting in the ceiling void. The ceiling void was cold hence the ductwork was cold. Moisture condensed on the inside of the ducting and a colony of *L. monocytogenes* became established. Droplets of condensate containing *Listeria* dripped back through the extract grille into the production area and onto product.

Humidification, if required (e.g. in cheese maturation rooms), can be done by the use of either atomising humidifiers (where a fine mist of water vapour is introduced into the air flow) or by steam injection humidifiers.

Microorganisms including *Legionella* may grow in the water used for humidifiers, so regular cleaning and maintenance are essential.

#### **7.4.4 Issues associated with installation of additional air extraction (sucking air from drains, importance of provision of air inlets, etc.)**

It is vital to remember that, in the case of air extraction systems, 'what goes out must first come in'. There have been numerous instances where air extract hoods have been installed over cooking pans or other preparation procedures without consideration of where or how the extracted air is to enter the production room. Brown visited one factory where an extract hood had been installed and the only entry for the air was through the drainage system. As a result, contaminated air was being introduced into the room and the drains did not function, resulting in regular flooding of the floor. In another factory, a similar situation was seen but in this instance the air entering through the drainage system was from a sewer connected to the abattoir next door.

#### **7.4.5 Air distribution systems (air socks, ceiling vents and importance of correct location)**

Positioning of inlet and extract grilles is also important. Burfoot and Brown (2001) and Brown (2005) provide guidelines that demonstrate how poorly sited inlet and outlet grilles can lead to ingress of contaminated air from low to high risk through doorways and conveyor openings.

Textile air delivery systems, or air socks, are often used to deliver filtered, temperature-controlled air within high care or high-risk areas. There are various types of textile system with differing permeability, materials of construction and characteristics such as humidity resistance, antibacterial properties, fire resistance and antistatic properties. Advice on choice and types of systems available is given by Brown (2005) and Wray (2011). Textile delivery systems should be supplied with filtered air (e.g. F8 BS EN 779) so that the sock systems themselves do not act as filters. This will reduce the frequency of laundering.

#### **7.4.6 Issues associated with electrostatic charge**

The effect of electrostatic charge on the rate of contamination of plastic food containers was recognised as long ago as 1966 (Baribo *et al.*, 1966). It is also recognised that when plastic bottles are transported via airlines, they can attain high levels of electrostatic charge. For example, Brown (2001) was called upon to investigate why a producer had been experiencing higher than expected levels of microbial contamination in product in polyethylene-terephthalate (PET) bottles. A sample of the bottles (neck i.d. 22 mm) was obtained and divided into two lots. One lot was handled, taking



no precautions to earth the operative or the bottles. Personnel with wrist earth straps handled the second lot in an earthed aluminium box. Both sets of bottles were then challenged with an aerosol of bacterial spores. Those bottles that were earthed had counts of between 1 and 6 from rinse water (inside the bottles) while those that were not earthed produced counts from rinse water of 58–94. Brown subsequently visited the factory and using a small hand-held field meter (JCI Chilworth, Southampton) measured voltages of several thousand volts from PET bottles as they were leaving blow-moulding machines. In some areas the reading was off the scale of the instrument ( $>20\,000\text{V}$ ). Airborne microorganisms, particularly mould spores, were being attracted into the bottles from at least 2m away. In addition the electrostatic charge was causing bottles to fall over on the conveyors as bottles repelled each other. Instead of transporting the bottles on open conveyors before filling, covered conveyors with filtered air supply had to be installed at the site to solve the problem of contamination.

In another part of the same factory, operatives were receiving regular electric shocks from a large roll of polythene used to wrap the bottles, as it was unrolled from the roll. Separation of the polythene from the roll was producing a large ‘triboelectric’ charge that was earthed when the operatives touched the roll. The problem was easily resolved by installing an earthed carbon fibre brush that gently brushed and earthed the roll surface as it rotated.

Problems of dust and airborne microorganism attraction to plastic materials by static electricity and other issues related to static charge can now be solved using DC pulse devices, static discharge resistors and ionisers.

## 7.5 Process air control

Process air may be low, medium or high pressure depending on the application. Low-pressure process air may be used for laminar flow enclosures for fillers, air to tank headspace, fluidised beds and spray dryers. Environmental HEPA filters would normally be used for these systems. Medium-pressure air would be used where it is to come into contact with the product but not be added to it, such as in air conveying. Either cartridge or environmental filters may be used depending on the working pressure. The level of filtration used for air to transport product should be higher than the level of filtration in the room in which the product is handled. This is because there is a higher level of risk of contamination to the product from air directly mixed into the product than when the product is exposed to contamination via sedimentation alone. High-pressure process air is designed to be included in the product, for example in whipped products, or used to purge product from process systems. The 3-A Sanitary Standards divide air under pressure into low ( $<150\text{ psig}$ ) and high ( $>150\text{ psig}$ ) pressure systems (Anon., 1995).

Process air that is delivered directly to the food product and pneumatic equipment may be filtered using cartridge filters (Brown, 2005). The choice of filter should ensure that it is suitable for food use and is robust enough for the particular application. There is no British or European standard for comparison of filter cartridges from different manufacturers. Efficiency levels are very high in comparison to environmental air filters, with removal efficiencies in excess of 99.99999999% when presented with a bacterial aerosol challenge.

Care should be taken to ensure that air supplied from compressors to pneumatic equipment in high-care and high-risk areas is filtered. This also includes air that is used to 'blow dust' from containers before packaging.

## **7.6 Air disinfection systems**

There is now a desire to supplement traditional, targeted chemical disinfection with alternative approaches which will control both the air and exposed surfaces in a processing area in its entirety, a technique that can be termed whole room disinfection. Novel disinfection techniques that are able to disinfect whole areas have been implemented in the pharmaceutical and clinical sectors, but there is limited information on the ability of these techniques to be applied to the food processing environment (Malinowska and Holah, 2010).

The range of techniques designed for whole room disinfection is increasing, but those that are commercially available include:

- chemical fogging;
- hydrogen peroxide vapour;
- ozone;
- chlorine dioxide;
- ultraviolet light;
- ionisation.

The critical factors to address before using these techniques include identifying areas where the decontamination processes can be applied, health and safety issues related to using the technique, any effect on the fabric of the equipment and the environmental building materials, and the practical considerations related to their use in the food processing environment.

### **7.6.1 Disinfectant fogging**

The purpose of fogging a production area is to reduce the numbers of airborne microorganisms and also to apply disinfectant to surfaces that may be difficult to reach (such as overhead surfaces). Applications include freezers, chillers, ripening rooms, process lines and production areas.

Manufacturers of salads, sandwiches, ready meals and dairy products frequently use some form of fogging.

There are various types of fogging systems available. They aim to disperse an aerosol of disinfectant into the air of the production area after cleandown. (Fogging must not be regarded as a replacement for traditional cleaning and disinfection routines.) Personnel are usually excluded during this procedure. Research carried out under the UK Advanced and Hygienic Manufacturing Link Programme (Burfoot *et al.*, 1999) demonstrated that fogging is effective in reducing the number of microorganisms on upward-facing surfaces but, in general, is not effective on vertical or downward-facing surfaces. The fogging was most effective when the median diameter of the fog droplets was between 10 and 20  $\mu\text{m}$ . Droplets in this size range dispersed well and settled within 45 minutes. The results of the study of the effectiveness of disinfectant fogging were also published by MAFF (1998) as a practical guide.

### 7.6.2 UV treatment

UV light can be used for air disinfection. The germicidal wavelength is approximately 254 nm. There are low-power systems with lamp ratings of 15–100 W and more powerful medium-pressure arc tubes with ratings of 0.5–5 kW. Burfoot (1999) reports the use of a UV system that could achieve kill rates over 99% in air flows up to 2 m<sup>3</sup>/s. It is important to avoid shadowing because microorganisms in the shade will not be destroyed. The dose required for one decimal reduction varies widely between species, from 2 mW s/cm<sup>2</sup> for vulnerable bacteria like *Legionella pneumophila* to 132 mW s/cm<sup>2</sup> for *Aspergillus niger* (Brown, 2005). High-intensity UV can cause skin cancer and cataracts of the eye. Proper screening from operatives and interlock devices are therefore an essential part of the design system.

The mathematical modelling of germicidal effect of UV is complex and the reader is referred to articles by Kowalski *et al.* (2000) and Kowalski (2001, 2006). Appendix A in the Kowalski (2006) article lists the D90 values of many microorganisms.

### 7.6.3 Ozone

There is a lot of interest in the use of ozone for air disinfection. Kim and Yousef (2000) tested ozone against *Pseudomonas fluorescens*, *Escherichia coli* O157:H7, *Leuconostoc mesenteroides* and *L. monocytogenes*. Exposure to 2.5 ppm for 40 s produced 5–6 log decrease in numbers, with *E. coli* O157:H7 being the most resistant. Work by Taylor and Chana (2000) has indicated a 2 log reduction in both airborne and surface adhered *Pseudomonas aeruginosa* in 2 h when exposed to 2 ppm ozone.

Ozone is toxic to humans and even at 0.5 ppm can cause nausea and headaches. At 50 ppm, 30 minutes exposure can be fatal. The Health and

Safety Executive (HSE) Guidance Note EH 38 (HSE, 1996) recommends an exposure limit of 0.2 ppm as a 15 min average for short exposure. Care should be taken to ensure that operatives are not exposed to levels of ozone above the recommended limits. Ozone disinfection is most effective at high (80–100%) relative humidity levels.

#### **7.6.4 Hydrogen peroxide**

Hydrogen peroxide demonstrates a broad spectrum of efficacy against viruses, bacteria, mycobacteria, fungi and bacterial spores, but is less effective if microorganisms are catalase positive. Hydrogen peroxide has been used for many years for sterilisation of packaging material (Smith and Brown, 1980; Leaper, 1984a, 1984b).

HSE EH 40 (HSE, 2005) recommends a short (15 min) exposure of 2 ppm for operatives and a long (8 h) time weighted average of 1 ppm.

### **7.7 Air sampling**

Air sampling in food manufacturing environments can be undertaken for three main reasons. Firstly, during process development, it is useful to record the number of microorganisms in the air throughout the production day to establish whether events occur that lead to high microbial counts, e.g. cleaning or opening external doors. Such events can then be controlled. Secondly, when a process has been established, the contribution of the air in terms of microbial cross-contamination to the product can be determined. This may have an effect on determining any additional controls necessary, particularly if the contribution is significant compared to other cross-contamination vectors (food contact surfaces, operative's hands, etc.) Thirdly, air sampling can be used to verify the performance of specific prerequisites designed to control airborne microbial levels, such as air filtration systems or assess the ongoing risk of potential microbial aerosol sources such as evaporative condensers.

There are numerous methods for determining the number of microorganisms present in the air (Miettinen, 2005; Wirtanen *et al.*, 2002). Some of those used in food factory environments are described below.

#### **7.7.1 Exposure or settle plates**

Exposure plates are the simplest devices for air sampling. Petri dishes containing either plate count agar or selective media are exposed for a given time interval, incubated and colonies counted. The exposure time depends on the cleanliness of the environment being sampled but exposures up to one hour in factory environments are usually sufficient. If exposure plates are distributed around a production environment and exposed for a

set time and positions noted, then areas of high airborne counts can be identified. Note that only microorganisms that settle on the agar are collected. Those that remain airborne will not be collected. In this respect settle plates are useful indicators of the number of airborne microorganisms that may land on an open product surface. They are particularly useful for collecting aerosols consisting of larger droplets, e.g. from floor cleaning or washing where the droplet size is large.

Wirtanen *et al.* (2002), citing Griffiths and Decosemo (1994), state that settle plates are simple to use but not quantitative and unreliable. However Pasquarella *et al.* (2000) argue that settle plates provide a more meaningful index of microbial airborne contamination risk than active air samplers. In their studies, settle plates produced data with lower standard deviation than active air samplers. They argue that settle plates have often been dismissed compared to active air samplers because the results are usually lower. However, settle plates count those organisms that land, whereas active air samplers count those that are airborne. In a food production situation where open product is on a conveyor line, it is the organisms that actually land on the product that are of interest rather than those that remain airborne.

Brown (2001, 2005) used settle plates successfully in both laboratory and factory environments. The settle plate method is a useful technique because it gives information of how many organisms land on  $63.6\text{ cm}^2$  of agar surface ( $\pi r^2$  for 90mm diameter dish) in the fixed time. If the sample position is next to open product on a production line then it is possible to estimate how many airborne microorganisms land on the exposed product.

For example: 50 bacterial colonies are counted on a 90mm diameter ( $63.6\text{ cm}^2$  area) exposure plate after one hour next to a production line. The product is on open trays  $15 \times 10\text{ cm}$  ( $150\text{ cm}^2$ ) and is open for 15 minutes. In 15 minutes we would expect  $50/4$  colonies to land in the Petri dish but  $50/4 \times 150/63.6 = 29$  to land on the product in the same time. Media selective for coliforms, *Pseudomonas* spp., *Staphylococcus aureus*, yeasts and moulds have all been used successfully by Brown in factory studies using both settle plates and air samplers. Kure *et al.* (2008) compared general and selective media for recovery of airborne moulds in cheese production and concluded that the selective media in their study was more appropriate to use.

### 7.7.2 Impaction methods

A wide range of impact samplers are available including:

- the SAS ([www.cherwell-labs.co.uk](http://www.cherwell-labs.co.uk))
- Oxoid MAQS ([www.oxoid.com](http://www.oxoid.com))
- Microbio ([www.parrett.uk.com](http://www.parrett.uk.com))
- Merck ([www.merck-chemicals.com](http://www.merck-chemicals.com))
- Sartorius ([www.sartorius.com](http://www.sartorius.com)) and
- the Andersen sampler.

Impact samplers usually sample selected volumes of air and are better at collecting larger particles. Some continuously sample over a timed period while the Andersen sampler splits counts into size fractions.

Impact samplers work by drawing air through a sieve plate or through a slit over a Petri dish or 55 mm diameter contact plate containing agar for a fixed time or volume.

Critical factors in their use include the following:

- The agar must be dispensed to ensure that each dish contains the same amount and that the depth of agar is controlled. Refer to each manufacturer's data. Variation in the depth of agar changes the distance between the top of the agar surface and the inside of the sampler head. This in turn changes the air velocity inside the sampler and changes the particle size collected. The agar can be dispensed while hot using a timed dispenser in order to standardise the depth of agar. If the depth of agar is too deep then the centre of the plate will have with fewer colonies than expected.
- The air speed through the sampler is critical in determining the particle size being sampled. Therefore the air velocity through the sampler needs to be checked periodically using a calibrated anemometer. Note that not all samplers work the same. Some sample a fixed volume and the fan speed may vary during sampling because the fan speed is monitored inside the equipment using an electronic rev counter. The fan speeds up or slows down to ensure the correct volume of air is sampled in the set time. Others sample for a fixed time. Some have variable speed settings. Therefore it is not always possible to compare counts using different samplers or even in some cases to calibrate them easily using an anemometer.
- Different samplers have different numbers and patterns of holes as well as different sizes of hole in the sampling heads. This can lead to different samplers collecting different particle sizes. The air velocity through individual holes in the sampling head determines the particle size collected. Samplers with variable fan speed settings will collect a different range of particle sizes at different speeds. The faster the fan speed the greater number of smaller particles that can be collected.
- The correct way of recording a count from an air sampler that has a sampler head with holes is to record the **number of positive holes NOT the number of colonies**. It is useful therefore to draw a grid pattern of the sampler head holes on a piece of transparent film that can be placed on the plate counter to aid the counting of positive holes after incubation.
- A correction chart is usually provided by each manufacturer to 'correct' for the chance of more than one microorganism going through the same hole and forming just one colony. As airborne concentration increases this becomes more likely so the correction charts give a bigger correction factor for higher counts. (If the counts are too high simply sample for a

shorter time period and vice versa.) The aim should be to get less than the total number of holes positive.

- **If individual colonies are counted instead of number of positive holes then do not use the correction charts.**

#### *Correction charts for impact samplers*

The correction charts for sieve-plate samplers are based on the fact that as the number of viable particles being collected increases then the probability of the next particle going through an empty hole decreases (Andersen, 1958; Macher, 1989). The values in the tables are calculated from the basic formula:

$$Pr = N[1/N + 1/(N-1) + 1/(N-2) + \dots 1/(N-r+1)]$$

where  $Pr$  is the expected number of viable particles to produce  $r$  positive holes and  $N$  is the total number of holes in the sampler head. Most manufacturers use this formula to create their correction tables. However this formula assumes that the flow of particles stops the instant a particle enters the  $r$ th hole. In practice the flow stops at random so the correct expected numbers of particles present if  $r$  positive holes are observed would be equal to or greater than  $Pr$  but less than  $Pr + 1$ . On average this would be  $[Pr + (Pr + 1)]/2$ . Very few correction tables use this extra correction factor but it is worth checking.

#### *Calibration of impact samplers*

In principle if air samplers are running too slow (air velocity too low) then only the larger airborne particles will be collected. As the air velocity is increased, then smaller and smaller particles will be collected. This is the principle behind the Andersen sampler (Andersen, 1958). As the hole sizes in the Andersen sieves get smaller, the air velocity increases and smaller particles are collected. Therefore setting a  $\pm$  tolerance for the calibrated air velocity has the following effect: if the velocity should be 18 m/s and a lower tolerance is set of, for example, 16 m/s then fewer airborne particles will be collected at this speed because only the larger particles will be collected. If an upper tolerance is set of, for example, 20 m/s then more particles will be collected because more of the smaller particles will be collected. So setting  $\pm$  tolerances for calibration affects both the size and numbers of particles the air samplers can collect.

When calibrating air samplers ensure they are fully charged (they work best if connected to the chargers). Always set them up so that the blades of the air velocity meter used to calibrate them are horizontal because they works best in this orientation at low speeds. The air velocity meter is fixed to the air sampler using a short section of plastic pipe taped in place.

The SAS samplers have a detector in the electronics so that during sampling, if the fan runs too slow then it automatically increases the sampling time to compensate and if it runs too fast it will shorten the time. This ensures that the correct volume is sampled. However it also means



that speed of the fan may vary during sampling that makes calibration a bit more complicated. This is why several readings are taken and average speed calculated. Cherwell labs offer a calibration service for these. These sample at 90l/min. The Microbio airspeed can be adjusted by means of one of the small screws on the circuit board inside. The sampling rate is set at 90l/min.

Oxoid sell a device to calibrate their MAQS samplers. The Oxoid samplers can run at various sampling rates (30, 60, 90, 120l/min, etc.) set by the operator. Changing the rate affects the size of particles collected. Mostly they are used at similar speeds to the others. There is a section in the manual on calibration explaining the use of the up and down arrows on the control panel of the sampler to increase or decrease the fan speed.

#### *Andersen sampler*

Andersen (1958) describes in detail the operation of the Andersen sampler. It is important to assemble the multistage samplers with the largest size hole at the top. Care should be taken to keep all the holes clear using a fine wire (e.g. guitar string) if necessary to clear the holes. The sampling rate is 1 cu ft/min (28.31 l/min). The Andersen sampler proved very useful in studies on aerosols produced during cleaning operations because information could be gathered on the particle sizes containing bacteria being formed during cleaning and which particle sizes remained airborne longest (Burfoot, 2005). It has been used in factory environments but waterproof plugs and extension leads must be used in this environment together with residual-current device (RCD) protection.

#### *Mattson–Garvin slit sampler*

The Mattson–Garvin model 220 air sampler (Barramundi Corporation, Florida) is primarily a research-based sampler and allows sampling for up to 1 hour. It samples at 1 cu ft per min (28.31 l/min or 0.0004719 m<sup>3</sup>/s). The airflow speed is set on the Mattson by ensuring the ball bearing in the gauge on the front is aligned to the centre of the red line by adjusting the screw above the gauge. It is also important to keep the slit clean using a thin piece of metal or plastic. Another important factor is to ensure that the agar is dispensed to the correct height in the 150 mm diameter Petri dishes. It is possible to adjust the height of the turntable to allow for different agar depths but it is much simpler if the agar in all Petri dishes is at the same level. In use, a line is drawn vertically on the side of the base of the Petri dish and this marks the start point when this is lined up with the slit. Note down also the direction of rotation. The plate can be divided into segments for counting to produce counts per 10 min intervals for example. It proved particularly useful in recording changes in airborne count e.g. before and after shift change at a hand-wash station. It has been used in factory environments but waterproof plugs and extension leads must be used in this environment together with RCD protection. Mattson also produce a compressed gas sampler.



### *Centrifugal samplers*

Centrifugal samplers have a propeller that pulls air into the sampling unit and pushes the air outward to impact on a tangentially placed strip of nutrient agar set on a flexible plastic base. Particles containing microorganisms in the incoming air are thrown out of the airstream by centrifugal force to be captured on the agar surface (Ljungqvist and Reinmüller, 1998).

The Reuter centrifugal sampler (RCS) is a portable, hand-held instrument that is used in the food industry (Griffiths and DeCosemo, 1994). Placencia *et al.* (1982) showed that the RCS yielded significantly higher recoveries than the Mattson – Garvin slit to agar sampler. Macher and First (1983) reported that the cutoff size of the sampler was above 3 µm and recommended its use for particle sizes of 5 µm and above. However Benbough *et al.* (1993), in a comparison with the Casella slit sampler found that a later model the Biotest RCS Plus sampler, was of comparable efficiency with only gradual fall-off of capture of particles below 4 µm.

### **7.7.3 Filtration samplers**

The Sartorius filtration sampler draws air through a membrane filter and this is then placed onto the appropriate agar and incubated. It works well for bacterial spores and mould spores because these survive well the dehydration during sampling. Bacteria more sensitive to dehydration may not survive so well. It has been used in factory environments but waterproof plugs and extension leads must be used in this environment together with RCD protection. Parks *et al.* (1996) recovered viable *B. subtilis* var. *niger* spores from monodispersed aerosols between 0.7 and 1.0 µm with an efficiency of 99.9995%.

### **7.7.4 Cyclone samplers**

Cyclonic air samplers (e.g. Coriolis and Burkard) use liquids to capture airborne microorganisms in a cyclonic sampling device. For 'rapid response' collection of large quantities of air (1200 l/min) there is the SAS cyclone. The liquids can then be cultivated or subjected to ATP or other analyses. Cyclonic air samplers with glass components are not suitable for food factory use.

## **7.8 Guide to maximum airborne counts for different product contamination rates**

Aerosol particles settle out due to gravity at a rate that is dependent on particle diameter and density (Cox, 1987; Cox and Wathes, 1995). The formula for settling velocity  $V$  is given by (Roberts, 2008):

$$V = \rho.d^2.g.C/18.\eta$$

where  $\rho$  = particle density ( $\text{g/cm}^3$ )

$d$  = particle diameter (cm)

$g$  = acceleration due to gravity ( $981 \text{ cm/s}^2$ )

$\eta$  = viscosity of air ( $18.2 \times 10^{-5} \text{ g/cm s}^{-1}$ )

$C$  = Cunningham slip factor (add  $0.08 \mu\text{m}$  to diameter as an approximation to calculate terminal velocity or use formula below)

$$C = 1 + 2.52\lambda/d$$

where  $\lambda$  = mean free path of air ( $0.07 \mu\text{m}$ )

The Cunningham slip correction factor is applied to correct for the fact that a discrepancy occurs as particle size decreases and approaches the mean free path of air molecules and particles slip between them.

Cox (1987) calculated settling velocities for particles of 1, 2, 3, 5, 10 and  $20 \mu\text{m}$  to be 0.0035, 0.013, 0.029, 0.078, 0.3 and  $1.2 \text{ cm s}^{-1}$  respectively.

Lungqvist and Reinmüller (1997) from studies on the relationship between airborne count and settle plate count used the formula:

$$N_d = V_s.C_b.A_e.T_e$$

where  $N_d$  = number of bacteria-carrying particles deposited onto a surface

$V_s$  = settling velocity ( $\text{cm s}^{-1}$ )

$C_b$  = concentration of bacteria-carrying particles in the air (number per  $\text{m}^3$ )

$A_e$  = area of exposed surface ( $\text{cm}^2$ )

$T_e$  = exposure time

Brown (2001) used this formula to compute a conversion factor 'x' between the number of bacteria-carrying particles landing during 1 h on a standard 90mm diameter Petri dish and an airborne count from an air sampler taken at the same time (Table 7.4).

For example, in an experiment using a Mattson Garvin air sampler, the mean airborne count was  $598/\text{m}^3$ . Ten settle plates open for 1 h alongside the air sampler gave a mean count of 58.1. Using a particle size of  $12 \mu\text{m}$  diameter as typical from Lungqvist and Reinmüller (1997) the conversion factor 'x' of 9.992 was used to calculate the airborne count. Thus  $58.1 \times 9.992 = 580/\text{m}^3$  which is close to that from the Mattson–Garvin count.

In another experiment, an aerosol of *B. subtilis* spores was created using a Collision nebuliser. The mean count from the Mattson–Garvin was  $3687/\text{m}^3$  and the mean settle plate result was 58.9 from ten settle plates exposed nearby for 1 h. Dividing 3687 by 58.9 gives 62.59 as the conversion factor 'x'. This equated to a particle size of just below  $5 \mu\text{m}$  which was close to the typical particle size generated by the nebuliser.

Brown (2001) produced a table of maximum acceptable count of airborne microorganism carrying particles that would result in at least one spoilt pack in 100 after 1 s exposure for different pack sizes. (Table 7.5).

**Table 7.4** Calculation of settling velocity and settling heights for bacteria-carrying particles between 1 and 20  $\mu\text{m}$ 

Particle diameter ( $\mu\text{m}$ )	Settling velocity (cm/s)	'x' where $\text{Cb} = 'x'.\text{Nd}$	Settling height in 1 hour (cm)	Volume above 9 cm diameter Petri dish for settling heights in column 5 (l)
1	0.0035	1250.12	12.57	0.799
2	0.0130	337.033	46.64	2.967
3	0.0284	153.709	102.27	6.505
4	0.0498	87.594	179.45	11.416
5	0.0773	56.503	278.20	17.698
6	0.1107	39.445	398.51	25.352
7	0.1501	29.089	540.37	34.377
8	0.1955	22.335	703.80	44.774
9	0.2469	17.686	888.79	56.542
10	0.3043	14.351	1095.34	69.682
11	0.3676	11.877	1323.45	84.194
12	0.4370	9.992	1573.12	100.077
13	0.5123	8.523	1844.35	117.331
14	0.5936	7.355	2137.14	135.958
15	0.6810	6.412	2451.49	155.957
20	1.2074	3.616	4346.65	276.521

$\text{Cb}$  = Concentration of bacteria-carrying particles (number/ $\text{cm}^3$  or  $/\text{m}^3$ ).

$\text{Nd}$  = Number of bacteria-carrying particles depositing on a surface.

**Table 7.5** Guide to maximum acceptable airborne microorganism count per  $\text{m}^3$  that could result in deposition in 1 in 100 packs after 1 s exposure (Brown, 2001)

Open area of pack ( $\text{cm}^2$ )	Particle sedimentation velocity ( $\text{cm s}^{-1}$ )					
	0.0773	0.3043	0.437	0.681	1.207	2.532
	Particle diameter ( $\mu\text{m}$ )					
	5	10	12	15	20	29
5	25873	6572	4577	2937	1656	790
10	12937	3286	2288	1468	828	395
15	8624	2191	1526	979	552	263
20	6468	1643	1144	734	414	197
50	2587	657	458	294	166	79
100	1294	329	229	147	83	39

For example for 100 packs whose open area is  $100\text{cm}^2$ , and a 'typical' bacteria-carrying particle size of  $12\mu\text{m}$ , with a sedimentation velocity of  $0.437\text{cm s}^{-1}$ , and packs open for only 1 second, an airborne count of  $229/\text{m}^3$  would give rise to on average one contaminated pack. If the packs were open for 60s then  $229/60$  or approximately  $4/\text{m}^3$  airborne bacteria would be required.

## 7.9 Conclusion and future trends

Production areas within food factories are zoned or segregated for hygiene reasons or to separate products that may, for example, cause allergic reactions. Holah (2005) recommends that in general, high-care/risk areas should be as small as possible as their maintenance and control can be very expensive. This zoning will affect the design and operation of air handling systems.

Computational fluid dynamic (CFD) modelling has been found to be increasingly useful in solving existing problems with air movement and also in designing new factories. The guidelines document available from CampdenBRI, entitled 'Best practice guidelines on air flows in high-care and high-risk areas' (Burfoot and Brown, 2001) addresses the importance of locating air inlets, extracts, doorways and processing equipment in the optimum position.

Evidence from modelling studies of factory air movements show that control of the whole area is complex and almost impossible (Burfoot, 2000b). There is now considerable interest in localised control techniques (Burfoot, 2000a; Brown 2005). Using a localised chilled filtered air supply along the length of a test conveyor system, Burfoot and Brown were able to achieve typically 1/100 to 1/1000-fold reduction in contamination levels within the controlled zone (Brown, 2005).

Whole room disinfection procedures are also likely to be used more widely (Malinowska and Holah, 2010) to control airborne and surface contamination.

## 7.10 Sources of further information and advice

Organisations that can provide information and advice in the UK include CampdenBRI, The Chilled Food Association, the Heating and Ventilating Contractors' Association (HVCA), the Chartered Institution of Building Services Engineers (CIBSE), the Building Research Establishment (BRE) and the Building Services Research and Information Association (BSRIA). Safety is covered by the Health and Safety Executive (HSE).

In Europe, the European Hygienic Engineering and Design Group (EHEDG) produce a series of guidelines including Number 30: *Guidelines*

on air handling in the food industry which is summarised in *Trends in Food Science & Technology* **17**, 331–336.

One of the key reference books on airborne microorganisms is the *Bioaerosols Handbook* (Cox and Wathes, 1995). The key food industry guide is Guideline No. 12 of the Campden and Chorleywood Food Research Association, '*Guidelines on air quality standards for the food industry*' (Brown, 2005).

### 7.10.1 Useful websites

<http://www.ashrae.org>  
<http://bsonline.techindex.co.uk>  
<http://www.campden.co.uk>  
<http://www.cen.eu>  
<http://www.chilledfood.org>  
<http://www.cibse.org>  
<http://www.ehedg.org>  
<http://eurovent-certification.com>  
<http://www.legislation.gov.uk>  
<http://www.hse.gov.uk>  
<http://www.hvca.org.uk>

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## Hygiene control in the application of compressed air and food gases

**F. Moerman, Catholic University of Leuven – KU Leuven, Belgium and  
S. Dewulf, Dewulf Consulting, Belgium**

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**Abstract:** Mild processing and conservation techniques may put food at risk, requiring the need for good hygienic engineering and design practice, and the use of hygienically appropriate process aids such as food gases and process air. Excessive contamination of these process aids also may shorten the life of equipment systems and components. This chapter must provide insight in the risks associated with the application of compressed air in the processing of food, the automation of manufacturing processes and in powering tools and motors. Guidance is given of how to manage these risks in order to obtain food-grade compressed air of a purity in agreement with existing standards. Further, a description is given of how food gases, dry ice and liquid nitrogen should be hygienically produced, transported, stored, supplied and used; and procedures are provided to manage and preserve the quality of these food gases.

**Key words:** compressed air, food gas, dry ice, liquid nitrogen.

### 8.1 Introduction

The use of mild processing and conservation techniques is on the rise, driven by consumer demand for ‘fresh-like’ additive-free foods with high nutritional and sensorial quality. However, such techniques may put foods at risk. Good hygienic engineering and design practice and the use of hygienically appropriate process aids such as food gases and compressed air are therefore essential in order to exclude and reduce physical, chemical or microbiological contamination in the processing chain. As well as being a food safety risk, excessive contamination of process aids such as gases may also shorten the life of equipment systems and components.

The first part of this chapter will provide an insight into the risks associated with the application of compressed air in food processing and in the powering and automation of manufacturing processes. Guidance is

provided on how to manage these risks in order to obtain food-grade compressed air. The second part of this chapter describes how food gases, dry ice and liquid nitrogen should be hygienically produced, transported, stored, supplied and used. Finally, procedures for managing and preserving food gas quality are outlined.

## **8.2 Hygiene control in the supply and application of food safe compressed air**

### **8.2.1 Introduction**

Unlike food gases, which are provided by an external supplier and must conform to strict tolerances and quality specifications, compressed air is generated on-site by the food manufacturer. Many food manufacturers have their own internal quality standards based on good manufacturing practice (GMP) in order to deal with the potential hazards associated with the use of compressed air in food factories. This section aims to support food manufacturers in the identification of contamination hazards and provide necessary guidance on how food safe compressed air can be produced for direct or indirect contact with food.

### **8.2.2 Application of compressed air in the food industry**

Table 8.1 shows some typical applications of compressed air in the food industry. A clean, dry, reliable compressed air supply is essential, whether the compressed air comes into direct contact with the product or is used for some other purpose such as process automation, automotive power, packaging operations or as an ingredient in the generation of other gases on-site.

### **8.2.3 Regulations with respect to the use and quality of compressed air in the food industry**

In Europe, compressed air that comes into direct or indirect contact with a food product must comply with the General Food Hygiene and Safety Regulations Directive 93/43/EEC and Regulation (EC) No. 852/2004 on the hygiene of foodstuffs. A food safety management system based on the principles of hazard analysis and critical control points (HACCP) must be implemented, following the guidelines published by the European Commission Health & Consumer Protection Directorate-General. Many companies are furthermore adopting standards such as ISO22000:2005 (EC, 2005) in order to allow an easier auditing process for HACCP procedures.

HACCP risk analysis does not always take into account the compressed air system and the points at which it is used, when in fact there are some

**Table 8.1** Common applications of compressed air in the food industry

Type of operation	Application
Food processing operations	<ul style="list-style-type: none"> <li>• Aeration and foaming (e.g. ice cream; whipping cream)</li> <li>• Coating and decoration of food products with colourants, flavours, sugar, egg, chocolate, etc.</li> <li>• Moistening of food products</li> <li>• Spraying pans with vegetable oil</li> <li>• Fermenter sparge air</li> </ul>
Unit operations	<ul style="list-style-type: none"> <li>• Direct cooling and heating of food products</li> <li>• Dehydration and (spray) drying of food products and raw materials</li> <li>• Mixing and bubbling of liquids</li> </ul>
Transfer and movement of food products or raw materials	<ul style="list-style-type: none"> <li>• Air-assisted transfer of food products (e.g. loaves)</li> <li>• Propulsive sideward removal of out-of specification food (e.g. peanuts)</li> <li>• Pneumatic conveying of dry materials</li> <li>• Fluidized bed technology</li> </ul>
Bottling	<ul style="list-style-type: none"> <li>• Cleaning and drying the inside of bottles, jars</li> <li>• Air pressure filling</li> </ul>
Packaging	<ul style="list-style-type: none"> <li>• Blow-moulding and propelling of plastic bottles</li> <li>• Expanding and opening of flexible packages</li> <li>• Cleaning and drying of packaging, cans, etc.</li> <li>• Vacuum and modified atmospheric packaging</li> <li>• Propulsive sideward removal of out-of specification packaging</li> </ul>
Food preservation	<ul style="list-style-type: none"> <li>• Spraying anti-microbial agent(s) onto food products</li> </ul>
Operation of food processing equipment	<ul style="list-style-type: none"> <li>• Vacuum generation</li> <li>• Cabinet cooling to increase the life and performance of the electronic equipment</li> <li>• Pressure equalisation</li> </ul>
Cleaning and drying of process equipment	<ul style="list-style-type: none"> <li>• Washing and drying of containers, piping, process equipment and conveyor belts</li> </ul>
Motive force	<ul style="list-style-type: none"> <li>• Pneumatic tools</li> <li>• Air motors</li> </ul>
Control application	<ul style="list-style-type: none"> <li>• Instruments</li> <li>• Automated applications</li> </ul>

points in a food manufacturing plant where compressed air comes into contact with food products, with no subsequent controls to any hazards introduced by the compressed air. These points could be classified as critical control points (CCPs), meaning that measures must be taken to reduce the level of contaminants to acceptable levels, as outlined in section 6 of the Code of Practice of the British Compressed Air Society (BCAS, 2007).

In the United Kingdom, the BCAS and the British Retail Consortium (BRC) have jointly developed the Code of Practice for Food-Grade Compressed Air, which provides quality standards for compressed air and defines the permitted levels of dirt, water and oil in compressed air produced

for use in food and beverage manufacturing, with the specification based on ISO8573-1:2001. This Code of Practice also provides recommendations for the testing and maintenance of compressed air systems, but does not cover the quality of other gases such as CO<sub>2</sub> or N<sub>2</sub>. Following the Code of Practice is not mandatory, but allows companies to demonstrate that they have taken the necessary steps to control the quality of the compressed air, which can be useful if any legal issues arise as a result of quality incidents. Moreover, many UK retailers ask food and ingredient suppliers (even those based outside the UK) to demonstrate compliance with the Code of Practice.

In the US, the Food and Drug Administration (FDA) has established clear parameters for the use of compressed air in 21 CFR 110.40(g): 'Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives'. The 3-A Sanitary Standards Inc. (3-A SSI), together with the United States Public Health Service (USPHS), the Dairy Industry Committee of the United States Department of Agriculture (USDA), the FDA and the European Hygienic Engineering & Design Group (EHEDG) have drawn up '3-A Accepted practices for supplying air under pressure in contact with milk, milk products and product contact surfaces, No. 604-05'.

#### **8.2.4 Contaminants in compressed air**

The contaminants that may be present in compressed air can be grouped into the following categories: dirt (atmospheric dirt, solid particles, rust, pipe scale), oil (liquid oil, oil aerosols, oil vapour), water (condensed liquid water, water aerosols, water vapour), chemical pollutants (toxins, odorous compounds, volatile organic carbons, polycyclic aromatic compounds, sulphur oxides, nitrogen oxides, acid vapours, etc.) and microorganisms. Table 8.2 provides an overview of the four sources that generate or contain these contaminants.

Figure 8.1 further shows that contaminants can also be introduced during the installation and repair of the air system. Other factors that increase the likelihood of compressed air becoming contaminated are: failure of the air compressor, leading to the possible release of metal particles; the length and ageing of the air line; and significant differences in temperature between the indoor and outdoor environment. The largest amount of contamination coming into the system originates from the air receiver and system piping (Maeda, 2001).

#### **8.2.5 Contamination pathways**

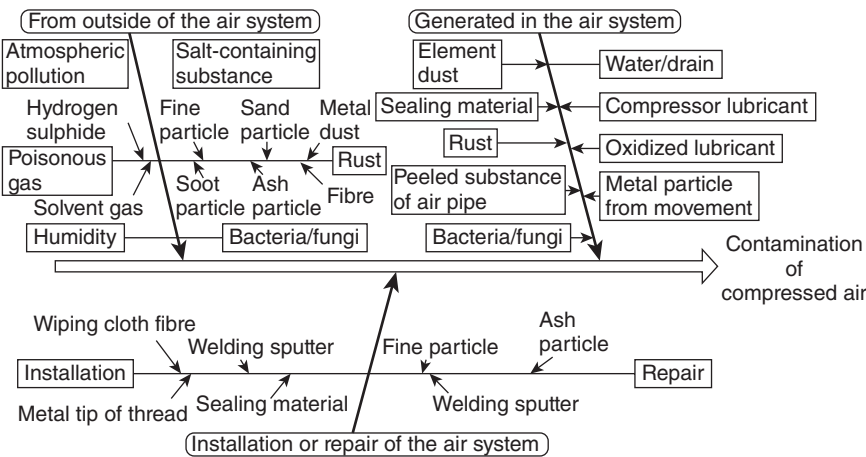
##### *Water vapour*

Water enters the compressed air system through the compressor intake as a vapour or gas. The amount of moisture in the air varies across different geographical locations, and from season to season: specifically, higher

**Table 8.2** Main sources of contaminants in compressed air, and the contaminants they generate/contain

Source of contaminants	Contaminants
Atmospheric air	<ul style="list-style-type: none"><li>• Water vapour</li><li>• Atmospheric dirt and dust</li><li>• Solid particles (plastic fragments, grit, glass, etc.)</li><li>• Pollen, allergens</li><li>• Chemical pollutants</li><li>• Oil vapour</li><li>• Microorganisms (bacteria and mould spores)</li></ul>
Air compressor	<ul style="list-style-type: none"><li>• Liquid oil, oil aerosols and oil vapour</li><li>• Condensed liquid water and water aerosols</li><li>• Coolants</li><li>• Wear and tear particles, metal particles in case of failure</li></ul>
Compressed air storage	<ul style="list-style-type: none"><li>• Water vapour and water aerosols</li><li>• Atmospheric dirt</li><li>• Oil vapour and oil aerosols</li><li>• Microorganisms (bacteria and mould spores)</li><li>• Rust and abraded metallic particles</li><li>• Pipe scale</li></ul>
Compressed air distribution piping	<ul style="list-style-type: none"><li>• Condensed liquid water, water vapour and water aerosols</li><li>• Liquid oil, oil aerosols and oil vapour</li><li>• Atmospheric dirt</li><li>• Microorganisms (bacteria and mould spores)</li><li>• Rust and abraded metallic particles</li><li>• Pipe scale</li></ul>

Source: Parker Hannifin – division domnick hunter (2009a).



**Fig. 8.1** Schematic overview of the potential causes of contaminants (Maeda, 2001).

relative humidity during the summer months results in increased water vapour in the compressed air system compared to the levels observed during the colder, drier winter months.

During compression, the temperature of the air increases significantly. Because compressed air is able to retain more water vapour at high temperatures, the water vapour will not precipitate inside the compressor during the compression cycle. However, when it meets the colder surfaces downstream, it may condense. The capacity of air to retain moisture as a vapour at a given temperature also decreases as the pressure increases.

#### *Condensed water and water aerosols*

Immediately after the compression stage, the aftercooler (often an integral part of the compressor) cools the air to within 10 or 15 degrees of the ambient temperature of 20–40 °C, depending on whether cold water, cold air or a refrigerant has been used as the cooling medium. This significantly reduces the capacity of the air to retain water vapour, which is instead condensed to liquid water or water aerosols. The primary function of an aftercooler is to remove water vapour rather than to lower the temperature of the compressed air.

Liquid water may be removed by a condensate drain fitted to the aftercooler water separator. However, the air leaving the aftercooler separator and entering the compressed air system is still 100% saturated with water vapour. Any further cooling of the compressed air, which may occur in the air receiver, the distribution piping and the valves, cylinders, tools and machinery, results in the production of more condensate. This can wash out protective lubricants in tools, air motors, equipment and pneumatic devices, leading to potential blockages and consequently also to higher maintenance, repair and operating costs. Although the condensate can be ducted away via drains in the compressor or at other points in the system, some droplets remain suspended in the air stream.

#### *Atmospheric chemical pollutants*

Fumes from industrial facilities that produce chemicals or combusting fuels, as well as exhaust emissions from vehicles contain chemical pollutants such as unburned hydrocarbons, polycyclic aromatic compounds, dioxins, sulphur dioxides, nitrogen oxides, carbon monoxide, carbon dioxide and so on. Their presence in food can pose a risk to consumer health; they may react with heat and water to form corrosive acids, and some corrosive volatile contaminants found in the exhaust of valves and other instruments can be hazardous for workers operating the plant.

#### *Dirt*

Atmospheric air in industrial and urban environments typically contains 180 million dirt particles (composed of dust, grit, carbon and pollen) per cubic metre. The size of the particles varies: only 20% are larger than

2µm, while the remaining 80% are smaller than 2µm, making them too small to be captured by the compressor air intake filter. Other particles, such as abraded metallic, rubber or plastic particles (for example, polytetrafluoroethylene, PTFE), may be generated in the compressed air system simply as a result of wear and tear, while others, such as welding sputter, metal dust or fibre cloth particles, are introduced into the compressed air infrastructure during installation or repair. Carbon products may also be formed through the action of the heat from compression on the lubricating oil, or through the normal wear of carbon piston rings used in some types of oil-free compressors. These dirt particles can have a number of undesirable effects: they can erode piping and valves, degrade rubber seals, cause valves and cylinders to stick, clog the passages of instruments, and contaminate the food product.

### *Oil*

When oil is present in pipelines, it can be in the form of a liquid (which creeps along the pipe wall), an aerosol (minute droplets of oil suspended in the air stream, with 90% 0.01 to 1µm in size) or an oil mist/vapour (vaporised oil in a cloud form). This oil, in whatever form, can taint products, labelling and packaging, giving them an oily smell, which can lead to increased waste and can also affect the health of plant workers.

Atmospheric air contains unburned hydrocarbon gases or oil vapour (in concentrations varying from 0.05 to 0.5mg per cubic metre), emitted by inefficient industrial combustion operations such as coke works and chimneys and by motor vehicles. As the air intake filter cannot retain the hydrocarbon gases and oil vapour, they are instead drawn into the compressor and compressed. The compressor oil may also vaporise and pass into the downstream system, where oil vapours may condense on the cooler surfaces of system components, forming a thin hardening film that may attract dirt and grit particles. The solidified mass that is formed as a result may then scour and damage the surfaces of moving parts such as cylinders, valves and tools during system operation.

The majority of air compressors still use oil in the compression stage, for sealing, lubrication and cooling. The compressor oil is generally degraded and oxidised by the heat generated in the compression process, creating a build-up of varnish on surfaces, or an often acidic substance. Liquid oil and oil aerosols mix with water in the system to form a thick, acidic, oily condensate, which can attack internal system components such as the rubber used in valve seals and the O-rings used in devices. A further consequence is friction between moving surfaces and corrosion of exposed metal components.

### *Microorganisms*

Atmospheric air can contain up to 100 million microorganisms per cubic metre. Bacteria, fungi, yeasts, spores (0.2 to 5µm), bacteriophages and

viruses ( $<0.2\mu\text{m}$ ) are drawn into the compressor air intake: due to their size, these usually pass through the compressor intake filters and enter the compressed air system. The compressed air storage and distribution system is warm and moist, thus providing an ideal environment for the multiplication of microorganisms. Many microorganisms and viruses are not killed by the heat generated by compression: bacterial spores may survive temperatures up to  $150^{\circ}\text{C}$ , while some mould spores can withstand  $100^{\circ}\text{C}$ .

A number of methods can be implemented to reduce the microbiological contamination of compressed air (Scott, 1998):

- Selection of an adequate location for the air intake of the air compressor, along with frequent analysis of the microbiological quality of the air at the intake point.
- Drying of the compressed air to a pressure dew point (PDP) of  $-26^{\circ}\text{C}$  and below in order to inhibit growth of microorganisms.
- Use of sterile air filters to reduce the concentration of microorganisms.
- Application of dry heat to sterilise compressed air. This involves passing compressed air through an oven at a temperature of above  $350^{\circ}\text{C}$ , but this is only successful at low air flow rates, making the method is time consuming and costly.
- Irradiation using ultraviolet (UV) light or X-rays, which can be applied at reasonably high air flow rates. However, this method is also costly, and the intensity and dwell times required make it an impractical choice except for very small applications. It should also be noted that spores are resistant to UV.
- Cleaning and disinfection of the compressed air infrastructure, for example, using steam.

#### *Rust and pipe scale*

The presence of water leads to the formation of rust and pipe scale in the compressed air receivers and the system distribution piping. This rust and pipe scale gradually breaks away, contaminating the compressed air and causing blockages or damage to the production equipment and contamination of processes and the final product. Rust and pipe scale are often observed after the installation of air dryers into older piping systems which had previously been operated with inadequate or no purification equipment.

### **8.2.6 Compressed air quality classes according to ISO8573-1:2010**

#### *Compressed air quality standard ISO8573*

The current international standard relating to the quality of compressed air is ISO8573. The nine key parts of this standard are given in Table 8.3. In addition, ISO12500 and ISO7183 series deal with the verification and



**Table 8.3** ISO8573 compressed air quality standard

ISO8573 – part No	Specification described
ISO8573-1:2010	Specifies the amount of contamination (dirt, water and oil) allowable in each cubic metre of compressed air at a particular point in a compressed air system
ISO8573-2:2007	Specifies the test method for oil aerosol content
ISO8573-3:1999	Specifies the test method for the measurement of humidity
ISO8573-4:2001	Specifies the test method for solid particle content
ISO8573-5:2001	Specifies the test method for oil vapour and organic solvent content
ISO8573-6:2003	Specifies the test method for gaseous contaminant content
ISO8573-7:2003	Specifies the test method for viable microbiological contamination content
ISO8573-8:2004	Specifies the test for solid particle content by mass concentration
ISO8573-9:2004	Specifies the test method for liquid water content

Source: Parker Hannifin – division domnick hunter (2009b).

benchmarking of the performance of compressed air filters and compressed air dryers respectively.

#### *Standard ISO8573-1:2010*

To specify the quality of compressed air, standard ISO8573-1:2010 outlines a system with 11 levels of purity, and establishes allowed limits for each of the three main contaminants (Table 8.4):

#### *Specification of the compressed air quality according to ISO8573-1:2010*

In any specification of air purity, the standard and date of issue must always be referenced, followed by the purity class selected for each contaminant. According to specification ISO8573-1:2010, Compressed Air Quality Class 1.2.1 corresponds to compressed air that contains  $\leq 20\,000$  particles  $0.1\text{--}0.5\mu\text{m}$  in size per  $\text{m}^3$ ,  $\leq 400$  particles  $0.5\text{--}1\mu\text{m}$  in size per  $\text{m}^3$ ,  $\leq 10$  particles  $1\text{--}5\mu\text{m}$  in size per  $\text{m}^3$ , a vapour pressure dew point of  $\leq -40^\circ\text{C}$  and a total oil content of  $\leq 0.01\text{ mg/m}^3$ .

### **8.2.7 Air purity requirements for compressed air used in the food industry**

For quality purposes, compressed air used in the food industry is divided into four categories:

- Compressed process air, which is directly incorporated into the product and hence requires a high level of contaminant control. The process air must be free of contaminants.
- Compressed air that is not intended to come into contact with food (also called non-contact), and which is emitted into the local atmosphere of

**Table 8.4** Permitted amount of contamination per m<sup>3</sup> of compressed air (ISO8573-1:2010)

Purity class	Solid particles			Water		Oil	
	Maximum number of particles per m <sup>3</sup> compressed air			Mass concentration (mg/m <sup>3</sup> )	Vapour pressure dewpoint	Liquid (g/m <sup>3</sup> )	Total oil (aerosol, liquid & vapour) (mg/m <sup>3</sup> )
	0.1–0.5 µm	0.5–1 µm	1–5 µm				
0	As specified by the equipment user or supplier, and more stringent than Class 1						
1	≤20 000	≤400	≤10	–	≤–70 °C	–	≤0.01
2	≤400 000	≤6000	≤100	–	≤–40 °C	–	≤0.1
3	–	≤90 000	≤1000	–	≤–20 °C	–	≤1
4	–	–	≤10 000	–	≤+3 °C	–	≤5
5	–	–	≤100 000	–	≤+7 °C	–	–
6	–	–	–	≤5	≤+10 °C	–	–
7	–	–	–	≤40	–	≤0.5	–
8	–	–	–	–	–	0.5–5	–
9	–	–	–	–	–	5–10	–
X	–	–	–	–	–	>10	>10

Source: Parker Hannifin – division domnick hunter (2009b).

the food preparation, production, processing, packaging or storage area. This is further subdivided into two categories:

- Non-contact low-risk compressed air is compressed air that will never come into contact with ingredients, food, beverages, packaging materials, storage vessels or manufacturing machinery.
- Non-contact high-risk compressed air is compressed air that is not intended to come into contact with these elements, but may inadvertently do so. An example of a high-risk area would be in the area of ready to eat food such as cut fruit salad.
- Instrument air, which is required for fine process instrumentation and controls that have a higher sensitivity to dirt, oil, crud and moisture. As the quality of plant air is not high enough to be used for this purpose, the Instrument Society of America has established the ISA-7.0.01.1996 standard, which offers guidance in the production of instrument-quality air:
  - Because the discharge of water in valves may cause short circuits in the solenoid wiring systems that activate the automation of the process equipment, the PDP must be at least 5 to 10°C below the minimum locally recorded ambient temperature (usually the winter temperature). In cold climates, a –40°C or even –60°C PDP is typical, requiring the use of a desiccant dryer. In warmer climates the PDP can be increased, but temperatures above –20°C should be avoided, because the expansion cooling effect of air leaking through a hole or in an equipment bleed can result in the build up of condensate and ice. The PDP must not exceed 2°C under any circumstances.
  - Particulate matter must be removed to below 0.02 mg/m<sup>3</sup> (size 100% < 0.01 µm).
  - Oil vapour must be removed to a residual level of 0.1–0.01 mg/m<sup>3</sup>.
- Plant air, which ranges from air compressed by means of a lubricated compressor without further treatment, to air that is filtered with at least the free water removed. This is used, for example, to drive pneumatic pumps and cylinders and air motors, to operate air-powered tools and to clean plant machinery. In cold climates, plant air can be dehydrated to a PDP of –40°C or less, but this is unusual.

Table 8.5 provides an overview of the quality required for the different categories of compressed air used in the food industry (BCAS, 2007; Parker Hannifin – division domnick hunter, 2009b).

## 8.3 Compressed air systems: components and location

### 8.3.1 Components of a compressed air system

A typical compressed air system (as shown in Fig. 8.2) consists of the following sequence of components: air intake filter, compressor, aftercooler,

**Table 8.5** Categories of compressed air used in the food industry, and the required air quality

Types of compressed air used in the production of food products	Sub-categories	Required air quality (class rating)
Process air	Air that comes into direct contact with the food or production process – critical applications	1.1.1–1.3.1 (sterile)
	Air that comes in direct contact with the food or production process – less critical applications	1.1.1–1.3.1 (non-sterile)
Air not in contact with food	Air that never can come in contact with the food or production process – no to low risk	1.4.1–2.4.1
	Air not intended to come in contact with the food or production process, but where contact may occur accidentally – high risk	1.2.1–2.2.1
Instrument air	Pharmaceutical, food and beverage, clean rooms	1.1.1–1.2.1
	Chemical, oil and gas, etc.	1.2.1–1.4.1
Plant air (general service air)	Pharmaceutical, food and beverage, clean rooms	1.1.2–1.3.2
	Chemical, oil and gas, etc.	1.4.2

Note: The contamination values for dirt, water and oil are those at the ‘reference conditions’ in ISO8573-1:2010 at a temperature of 20 °C, absolute atmospheric pressure of 1 bar and relative water vapour pressure of zero.

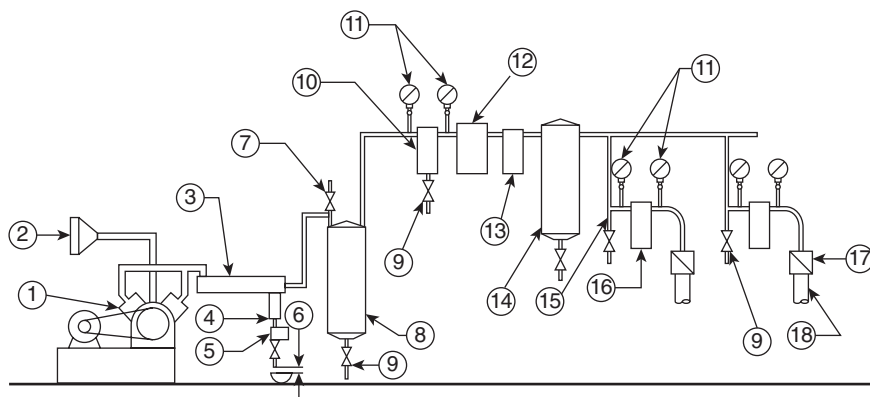
Source: Parker Hannifin – division donnick hunter, 2009a,b.

oil/water separator, wet air receiver, coalescing filter, air dryer and interconnecting piping, followed by a downstream distribution network to take the compressed air to the points of application. Additional filters such as activated carbon, dust and sterile filters may be installed in the downstream distribution network or at points-of-use.

### 8.3.2 Selection of an appropriate compressor

From a hygiene perspective, the choice of an oil lubricated versus a non-oil lubricated (or oil-free) compressor is the most important decision in selecting a compressor that meets the requirements of a particular application. In lubricated compressors, lubricating oils act as a seal between the compressor blades and the pressure chamber. In the non-lubricated type, a soft material such as Teflon® or carbon may form the seal and the oil is wholly confined to the compressor crankcase.

Faced with the choice between the two types of compressor, many food manufacturers select the oil lubricated type, because of lower initial costs



**Fig. 8.2** Layout of a typical compressed air system that meets the hygienic requirements of the food industry: 1 compressor, 2 air intake, 3 aftercooler, 4 water/oil separator, 5 drain trap with drain valve, 6 air gap, 7 hygienic relief valve, 8 wet air receiver, 9 drain valve, 10 coalescing filter, 11 pressure gauges (optional), 12 dryer, 13 dust removal/active carbon filter, 14 dry air receiver, 15 drip-leg, 16 point-of-use filter, 17 product check valve, 18 stainless steel sanitary piping connected to the food application (3-A, 2004).

and lower maintenance requirements. However, oil lubricated compressors require the use of food-grade lubricants, in accordance with EHEDG Doc. 23, 'Production and use of food-grade lubricants'. Food-grade (H-1) lubricants have a number of disadvantages, including a requirement to replace compressor oil more frequently, higher lubricant cost, and lower temperature resistance. Certain compressors employ lubricants in parts such as bearings and gearboxes that are not involved in the actual compression of the air. However, these compressors may also produce some oil mist, which may present a contamination risk. If any potential for contamination by vapours, aerosols or liquid oil is identified, the procedures described in EHEDG Doc. 23 should be implemented (Parker Hannifin – division domnick hunter, 2009a).

When the maximum oil contamination levels permitted correspond to ISO8573-1:2010 Class 0 or Class 1, then the use of oil-free compressors is recommended. According to the Code of Practice for Food-Grade Compressed Air, these oil-free compressors are not subject to the requirements of EHEDG Doc. 23, since no lubricant is involved in the compression process. However, it is a misconception that the installation of an 'oil-free' compressor into the system removes the requirement for downstream filtration. Oil-free compressors still compress the same contaminated air as oil lubricated compressors. In order to produce clean, dry, contaminant-free air required for contact with food products, these compressors still require the same in-line compressed air purification equipment as oil lubricated compressor installations (BCAS, 2007).

### 8.3.3 Indoor installation of the air compressor unit

The air compressor should preferably be installed in a location protected from the weather, ideally in an indoor technical area (such as a compressor room) as close to the food processing area as possible to minimize the length of the compressed air distribution piping. The longer the distribution piping, the greater the risk of water and oil vapour condensation, sludge and dirt deposition, pressure drop, and contamination of the compressed air due to the occurrence of leaks or the presence of microbial nidus. The number of bends and valves has a similar effect on risk levels and should therefore also be kept to a minimum. The following recommendations relate to the indoor installation of air compressor units:

- Compressors create heat, and hence should never be installed in food processing areas where a low temperature is required.
- Ventilation should be provided: the cooling air output of a compressed air system should be fed out to either an outdoor area or an energy recovery system. When heated air from the compressor remains around the unit and is then ingested by the compressor, the operating temperature of the unit rises, which can eventually lead to the shutdown of the air compressor. Areas that are extremely humid or where ambient temperatures exceed 40–45 °C should be avoided. At the other end of the scale, temperatures lower than 5 °C should also be avoided, because compressor safety devices may freeze.
- To allow maintenance, inspection and removal of the equipment when required, there must be approximately 1 m of space around the compressor units
- The air compressors and receivers should be installed on concrete plinths about 150 to 200 mm high, with sloped equipment drain trap discharge lines to the utility drains. The concrete plinths should extend a short distance (~75 mm) beyond the compressors and receivers, to allow for the safe separation of the equipment from personnel and passing maintenance vehicles.

### 8.3.4 Outdoor installation of the air compressor unit

Outdoor installation of an air compressor unit may sometimes be required due to conditions onsite or space limitations. The following recommendations relate to the outdoor installation of air compressor units:

- The compressor must be suitable for outdoor use, i.e. it must be weather resistant and able to be serviced outdoors.
- The cabinet exhaust should be on the end of the unit, rather than the top, to prevent recirculation of cooling air.
- Heaters and heat tracing key elements should be used in situations where slow start up and freezing (of condensate, for example) may be a problem.

- The compressor should be installed on a concrete pad designed to drain water away. If the concrete pad is sloped, the compressor must be levelled and the base/skid must be sealed to the concrete pad.
- The roof of the shelter should extend to a minimum of 1.2 m beyond the compressor on all sides to prevent rain and snow from falling on the unit. Air-cooled machines must be arranged correctly to prevent air re-circulation (for example, of the hot exhaust back into the package inlet).
- A minimum of 1 m clearance must be allowed on all four sides of the unit for service access.
- A fence or security protection system should be installed to prevent unauthorized access.

### 8.3.5 Location of the air intake

The location of the air intake is an important aspect of air compressor design. The key recommendations in this regard are as follows:

- Air should be drawn from a clean space or from relatively clean outer air, preferably from outside the building. This is because virtually all particles, vapours and gases in the air within a 1.2 m radius of the inlet can enter the compressor, and smaller particles of less than 10  $\mu\text{m}$  can be drawn in from an even larger radius.
- If air from an area inside the building is drawn into the compressor, then the temperature, humidity and presence of contaminants in that area should be as low as possible. To reduce the likelihood of contamination, the air compressor should not be installed in a technical room that contains waste products, chemicals, or equipment that emits smoke, for example. The doors to the compressor room should be closed to prevent the entry of dirty air from less clean adjacent areas.
- Food manufacturers should also bear in mind that building materials such as floor coverings and flooring adhesives can release indoor air pollutants, in particular volatile organic carbons (VOCs). The compressor and indoor air intake should be installed in a location constructed using building materials that produce only low levels of any potentially harmful substances. However, VOC emissions can also result from flooring maintenance and cleaning, and these can be significantly greater than those originating from the flooring material itself. Ideally, high-performance floor coatings should be used, which reduce the need for floor maintenance using chemicals.
- The design engineer should sample the air at the proposed intake location over a period of several months, covering different seasons and different times of day, in order to test for the presence of known and potential pollutants.
- Indoor air inlets should be positioned at least 1 m above any floor or dust-collecting surface and away from any other possible source of

contamination, in order to avoid dust or water droplets being drawn into the system. For outdoor installations, the inlet should ideally be mounted 3 m above ground or snow level, and no less than 1 m above the roof.

- A weatherproof covering and screen should be installed around and over the inlet, to prevent insects, leaves, dirt and rain from entering. The intake point should not be close to any exhausts or vents.
- The air intake should preferably be located outside in the coolest area, because cold air can increase the efficiency of the compressor. If the installation includes more than one compressor, the hot air exhaust should not be directed towards the fresh air intake of the second unit or towards an air dryer.

### **8.3.6 Technologies for removal of contaminants**

Large amounts of contaminants that have been drawn into the system may accumulate in the air receiver and system piping that store and distribute the compressed air. The best way to achieve a low level of contamination in these parts of the system is therefore to reduce the contaminant load in the intake air and to treat the compressed air prior to entry into the distribution system (usually in the compressor room or at the point of generation) to a specification that will provide contaminant-free air. Where required, point-of-use purification using purification equipment, filters and air dryers should also be employed to meet the air quality requirements for a given application. Table 8.6 provides an overview of the best available purification technologies for the removal of different contaminants.

## **8.4 Equipment to remove the bulk of water**

### **8.4.1 Aftercooler**

Air leaves the compressor at a temperature of between 110 and 200 °C, and is then passed through a water- or air-cooled aftercooler (Fig. 8.3) to cool the compressed air to a temperature 14 to 17 °C below ambient. The aftercooler serves to remove large amounts of water vapour from the air via a mechanical moisture separator, which is usually an integral part of the aftercooler.

### **8.4.2 Water and oil separator**

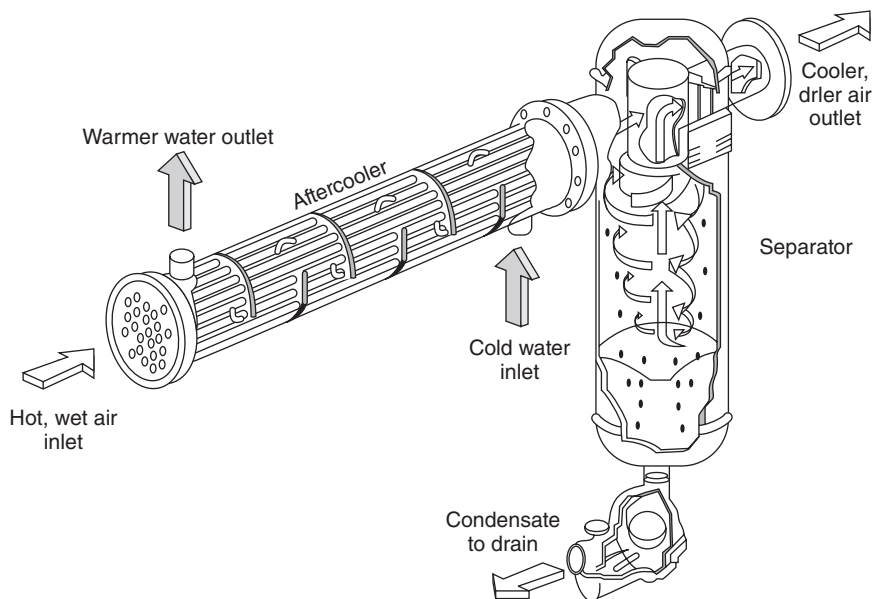
A separator (Fig. 8.3) should be installed after the aftercooler or compressor to strip large quantities of liquid water or oil from the airstream, either individually or as an emulsion. The separator should remove 90 to 99% by weight of the liquid present, in order to protect the downstream coalescing filter against bulk liquid contamination. Separators, however, are not suitable for the removal of vapour and aerosols of water and oil. They are also often installed after air receivers and distribution piping that is prone



**Table 8.6** Overview of purification technologies employed in the removal of certain contaminants

Purification technology	Contaminant removal						
	Bulk condensed water	Water vapour	Water aerosols	Atmospheric dirt and solid particles	Microorganisms	Oil vapour	Liquid oil and oil aerosols
Air intake filter				•			
Aftercooler		•					
Water and oil separator	•						
Wet receiver		•					
Coalescing filters			•	•	•		•
Adsorption filters						•	
Adsorption dryers		•					
Refrigeration dryers		•					
Dust removal filters				•	•		•
Microbiological filters				•	•		

Source: Parker Hannifin – division domnick hunter (2009a).



**Fig. 8.3** Typical aftercooler, moisture separator and drain trap (Frankel, 2002, with permission from McGraw-Hill).

to excessive cooling and hence to condensation, but should always be located before the purification equipment.

### 8.4.3 Wet air receiver

A wet air receiver serves to store compressed air, to handle sudden system demand surges, to allow both ordinary and emergency shutdown and to provide a surge volume for dryer purges. The wet air receiver is also another opportunity to condense and remove additional moisture from the compressed air, and to allow the separation of that moisture from the air. The wet receiver is usually installed just after the combined aftercooler/separator, and before the coalescing filter. The wet receiver must have adequate capacity and should be located in the coolest location available; it should not be situated within the compressor room. The ambient temperature is typically lower than the dew point of the air entering the receiver, which causes the moisture to condense inside the receiver. An air receiver must always feature an automatic liquid drain device to dispose of any moisture.

### 8.4.4 Drain traps

Drain traps should be fitted to support the aftercooler/intercooler moisture separators (Fig. 8.3), the wet receiver, the pre-filters (coalescing filters) and

certain dryers; these allow the collection and removal of separated water with little or no loss of line pressure or compressed air. The drain traps can be either manual or automatic. Manual traps are simply a length of pipe making up a drip leg installed at the bottom of risers; they have a valve that must be manually opened on a daily basis to drain the liquid. Unfortunately these manual drain valves are often left open, wasting large amounts of compressed air. Automatic traps are therefore a more common alternative, such as level-operated mechanical traps (float type and inverted bucket type), electrical operated solenoid valves and zero-loss traps with reservoirs. Care must be taken with the use of float-type drain traps, as these are prone to blockage from sediment in the condensate. Inverted bucket traps may require less maintenance but result in wasted compressed air if the condensate rate is too low to maintain the liquid level in the trap. With electrically operated solenoid drain traps, care must be taken to ensure that the valve is open for long enough to allow adequate drainage of the accumulated condensate. Moreover, these drain traps may remain open as a result of dirty seals or malfunctioning solenoids. Both level-operated traps and electrically operated solenoid valves should have strainers installed to reduce the level of contaminants, which can block the inlet and discharge ports of these automatic devices. To avoid blockage and the resulting accumulation of fluids, drain traps should have ports with an internal diameter of at least 10mm.

Each of the drain traps should have its own individual drain that discharges to a sump. If multiple drain traps are connected to a common discharge manifold, drains that release their fluids at higher pressure may hamper the correct draining of other drain traps that release fluids at lower pressure. In a worst case scenario, the fluids and dirt discharged at higher pressure may back-up in the other traps that discharge at lower pressure. The cleaner downstream parts of the compressed air system are at the greatest risk of this type of contamination, because the drains in this part of the system operate at lower pressure than the dirtier components upstream. This problem can be partially solved through the use of 'zero-loss' drain traps that release their fluids without wasting compressed air. All drains must have an air break, but must not allow the release of condensate and dirt into the food processing environment. Drained liquids should be treated to remove the lubricant before they are discharged into a sewer system or disposed as hazardous waste in accordance with local legislation.

## **8.5 Filtration and drying in compressed air systems**

### **8.5.1 Pre-filters**

Pre-filters are generally used before air enters a dryer to remove various contaminants that might foul the unit. Typical pre-filters are the air intake

filter, the general purpose filter and the high-efficiency oil removal filter (the last two are together referred to as coalescing filters).

#### *Air intake filters*

To avoid rapid wear of compressor parts, the intake air must be clean. Larger particles are caught by the compressor inlet filter, but airborne particles smaller than  $10\mu\text{m}$  can enter the compressor. In certain urban locations and industrial applications, air is often contaminated with corrosive and acid gases that are also able to pass through the air intake filter. High-efficiency air intake filters should be used, which can remove large amounts of particulates from intake air, allowing them to accumulate on the filter elements while maintaining low resistance to the flow of intake air and a low pressure drop. These filters should:

- have a large particulate storage capacity;
- have high mechanical and structural strength;
- be protected from weather, drainage, water, product spillage and physical damage;
- be located and constructed in such a way that allows easy examination;
- allow easy cleaning and replacement.

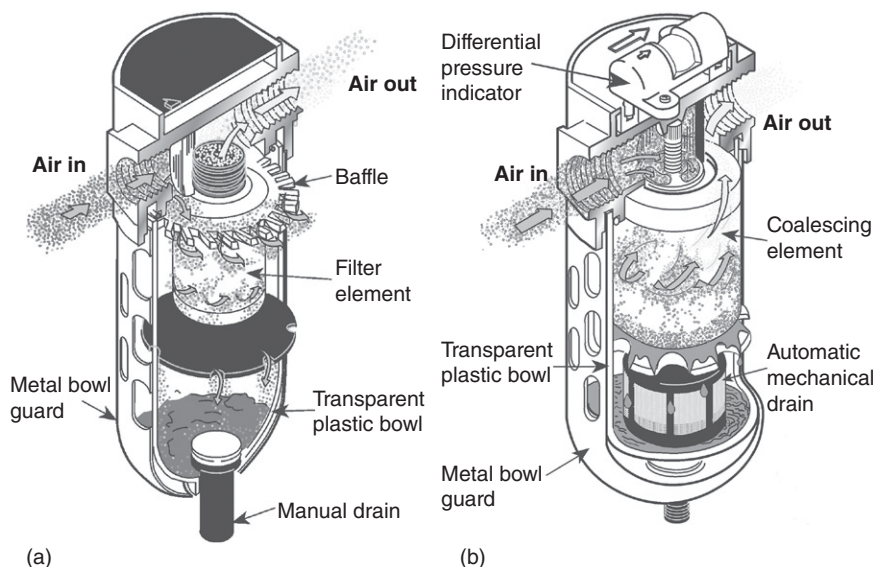
#### *Coalescing filters (general purpose filter and high-efficiency oil removal filter)*

The combined aftercooler-moisture separator removes large volumes of water, while coalescing filters are designed to remove aerosols (droplets) of oil and water, although not oil and water vapours, using mechanical filtration techniques. These filters may additionally remove contaminating particles as small as  $0.01\mu\text{m}$  in size.

Coalescing filters are in fact a pair of filters in series (Fig. 8.4(a) and (b)):

- A general purpose filter is used as an initial filter to protect the second high-efficiency filter from bulk contamination. The filter is able to remove bulk liquids and particulate matter down to  $1\mu\text{m}$ , and is therefore required by both non-lubricated and lubricated compressors.
- A high-efficiency filter is able to remove almost all water and oil aerosols, as well as fine particles down to  $0.01\mu\text{m}$  (the maximum remaining oil content in the exit air is usually  $0.01\text{ mg/m}^3$ ). Technical oil-free air can be obtained through the use of this filter, similar to that supplied by an 'oil-free' machine.

In the general purpose filter, the wet and dirty inlet air is directed downward and outward in a circular pattern by means of a turbine-shaped upper baffle, promoting the separation of large amounts of liquid and large particles. The liquid flows down the inside of the filter housing bowl and through a turbulence-free zone past a lower baffle; this method of drainage prevents the re-entrainment of fluids back into the clean compressed air.



**Fig. 8.4** The general-purpose filter (a) protects the second high-efficiency filter (b) from bulk contamination by removing bulk liquids and particulate matter down to  $1\mu\text{m}$ . The high-efficiency filter is able to remove almost all water and oil aerosols, as well as fine particles down to  $0.01\mu\text{m}$  (courtesy of Parker Hannifin – division Wilkerson).

The partially cleaned air then passes into the filtration media ( $5\mu\text{m}$  in depth), which provides superior filtration with minimum pressure drop.

In the high-efficiency filter, the air passes from the inside of a borosilicate micro-fibre filter element to the outside, with minimum pressure drop. The inner layer of the filter element acts as an integral pre-filter to remove large contaminants, protecting the next layer, which is composed of high-efficiency filter material which removes the majority of submicron aerosols and solids from the compressed air flow. In the filter, the solid particles are permanently trapped within the filter media, while the droplets that collide with the fibres collect or coalesce to form large heavy droplets. Gravity causes these droplets to be drained into the cellular structure of the filter. A wet band forms at the bottom of the filter element, creating a high-pressure drop area with higher resistance to air flow (a quiet zone with no air movement), which forces the compressed air to pass through the upper portion of the element and allows the liquid to fall to the bottom of the filter bowl. This movement of the liquid contaminants under the filter element away from direct air flow prevents the carryover of liquids in the air stream, as long as the liquid is quickly discharged via a drain (preferably automatic) installed at the base of the filter housing. If the coalescing filter is large enough, the compressed air may also exit the filter at low velocity, preventing carryover of the coalesced liquid in the air stream. Liquid must not flow from outside

to inside the filter tube, as this would cause the filter to quickly collect liquid on the inside of the filter tube, reducing its efficiency eventually to zero.

The coalescing filter and any traps should always be located downstream of the air compressor, aftercooler, water/oil separator and wet air receiver (if one is used). Since the air continues to cool in the distribution system, additional coalescing filters located at end-use points may be required to remove water (condensed downstream from the main line filter), dirt and oil. The filter should be installed immediately upstream of the pressure regulator, if one is fitted.

If a refrigeration dryer is used, a coalescing filter must be installed after it, because refrigeration dryers can only remove water vapour and not water or oil in liquid form. Whenever a desiccant-type dryer is used, a coalescing filter must be installed at the dryer inlet in order to remove the oil, which would otherwise render the compressed air desiccant dryer useless in a short space of time. With deliquescent dryers, a coalescing filter should be installed after the dryer.

### 8.5.2 Compressed air dryers

Water vapour passes through water separators and coalescing filters, and must therefore be removed by means of a dryer. The water vapour removal efficiency of a dryer is expressed in terms of the PDP, which is the temperature at which the air contains 100% of the moisture, which will then begin to condense on a surface. The PDP is used to express the dryness of the compressed air, and indicates that the ambient temperature that surrounds the compressed air distribution system above the PDP must be maintained in order to prevent liquid water from condensing inside the piping.

As an example, compressed air with a PDP of  $-20^{\circ}\text{C}$  requires the temperature to drop below  $-20^{\circ}\text{C}$  before any water vapour condenses into a liquid. A PDP of  $-40^{\circ}\text{C}$  is recommended for all food applications where air is in direct or indirect contact with production equipment, ingredients, packaging or finished products. The selection of the air dryer depends on the degree of dryness that is required for the process. Table 8.7 provides an

**Table 8.7** Compressed air dryers that are available on the market

Dryer type	Pressure dew point
Deliquescent dryer	$+10^{\circ}\text{C}$ to $+11^{\circ}\text{C}$
Refrigeration dryer	$+15^{\circ}\text{C}$ to $+3^{\circ}\text{C}$
Membrane dryer	$+4^{\circ}\text{C}$ to $-40^{\circ}\text{C}$
Desiccant heatless	$-40^{\circ}\text{C}$ to $-70^{\circ}\text{C}$
Desiccant heated	$-40^{\circ}\text{C}$ to $-70^{\circ}\text{C}$

Source: AMEI (2011).

overview of the compressed air dryers that are currently commercially available, and the PDP that they can produce.

### *Deliquescent absorption dryers*

Deliquescent dryers are a simple type of chemical dryer in which the compressed air is passed over soluble material such as a bed of salt (e.g. magnesium chloride, dehydrated chalk, calcium chloride or lithium chloride). These soluble materials dissolve as they absorb moisture, after which a semi-solid matter can be drained from the system. The deliquescent air dryer removes the lowest amount of water vapour, producing a PDP of between 10 and 11 °C ( $\approx 9.8 \text{ g moisture/m}^3$ ), which is about 6 °C below the inlet temperature. This type of dryer is therefore unsuitable for critical applications where the compressed air needs to be very dry. Although these dryers are energy efficient and incur the lowest initial cost of all dryers, they are more expensive to operate because the deliquescent material needs to be regularly replaced. Moreover, deliquescent dryers require oil/water filters in front of the dryer, and dust removal filters after the dryer (AMEI, 2011).

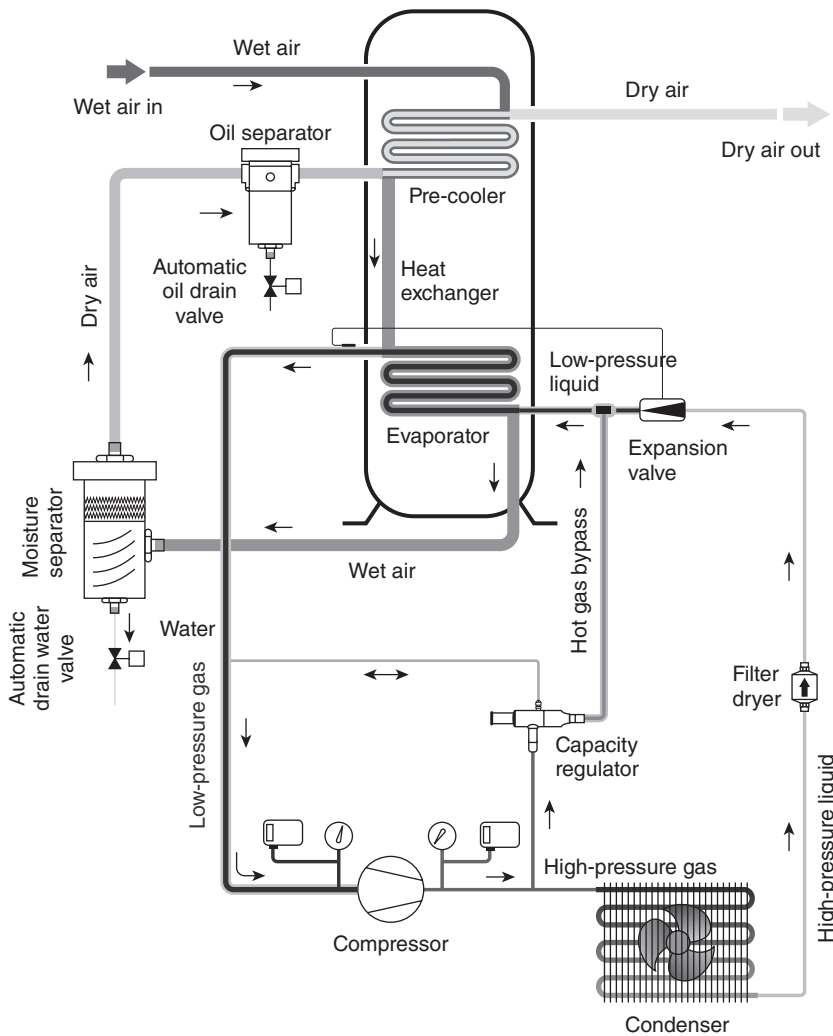
### *Refrigeration dryers*

Refrigeration dryers (Fig. 8.5) operate as heat exchangers, cooling the compressed air to condense the water vapour out of the circulating air onto the coils of the dryer. A large amount of oil and particles are also expelled along with the condensate. This liquid is then drained from the dryer by means of a separator and drain valve. The cooling medium used in the coil may be chilled water, brine or a refrigerant: dryers that use the last of these are the most common type, and are called refrigerated dryers.

The use of refrigeration dryers is restricted to positive PDPs of approximately +2 °C, otherwise the condensed moisture could freeze on the coils. If that occurs, the heat transfer process is seriously degraded by the film of frost on the coils, which acts as an insulator. Refrigeration dryers are not suitable for installations where piping is installed at ambient temperatures below the dryer dew point, i.e. systems with external piping. Refrigeration dryers producing compressed air with a PDP of 2 °C ( $\approx 6 \text{ g moisture/m}^3$ ) are also unable to inhibit microbial growth, which makes them unsuitable for critical applications such as food, beverage and pharmaceutical manufacturing (Frankel, 2002). A range of pre-filters with automatic drains must be installed before the refrigerated dryer to prevent oil and condensed water from entering the dryer: the oil could otherwise coat the cooling coil, thereby reducing its efficiency. A particulate filter, if used, should precede the refrigerated dryer (AMEI, 2011).

### *Membrane dryers*

Membrane dryers diffuse the moisture from the compressed air into the atmosphere using hollow fibre membranes. These membranes only allow



**Fig. 8.5** Refrigeration dryer (Frankel, 2002).

water molecules to pass as permeate, so that the air is dried. Membrane dryers are mostly used when low PDPs ( $+4^{\circ}\text{C}$  to  $-40^{\circ}\text{C}$ ) are required in localized areas of a system. The major disadvantages of this type of dryer are that the membranes are susceptible to oil and dirt, and that they cannot be cleaned and must hence be disposed of after the end of their useful life. They may also reduce the oxygen content in the compressed air, making them unsuitable for the production of clean air for breathing and fermentation processes. Membrane dryers are effective as a point-of-use dryer for very small quantities of compressed air, for non-continuous



operation, or in applications that do not involve electrical energy (AMEI, 2011).

### *Desiccant adsorption dryers*

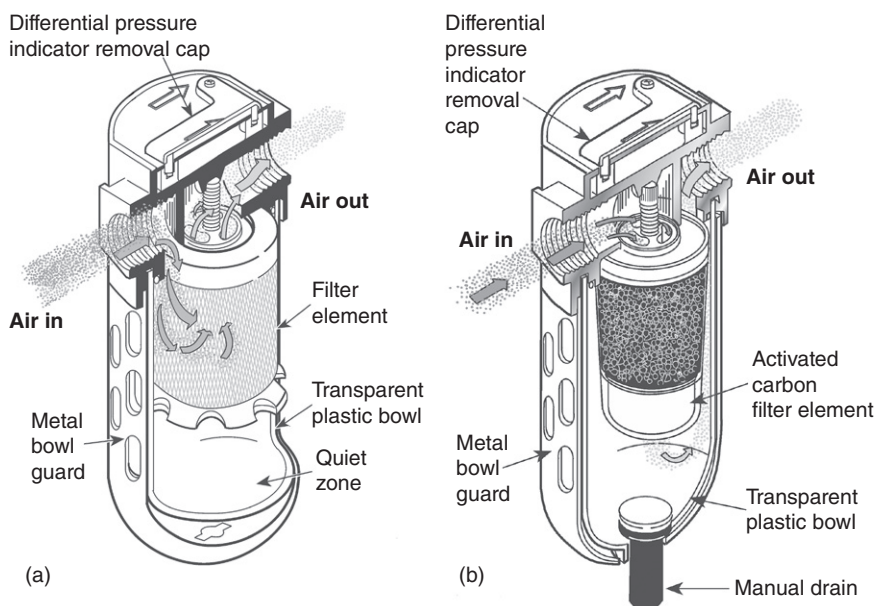
In desiccant adsorption dryers, air is passed over a regenerative desiccant material (such as silica gel, activated alumina or aluminium silicate) which strips the moisture from the air. A typical PDP specified for a desiccant adsorption dryer is  $-40^{\circ}\text{C}$  ( $\approx 0.12\text{ g moisture/m}^3$ ) as this both prevents corrosion and inhibits the growth of microorganisms. For critical applications, a PDP of  $-70^{\circ}\text{C}$  ( $\approx 0.002\text{ g moisture/m}^3$ ) is often required. A particulate filter should be installed after the desiccant dryer to prevent dust from moving downstream. The desiccant material has a finite capacity for absorbing moisture, and should be regularly regenerated (AMEI, 2011).

### 8.5.3 After-filters

After-filters are generally used after the drying process to remove smaller particulates than pre-filters.

#### *Dust removal filters*

Dust removal filters (Fig. 8.6(a)) are commonly used with desiccant dryers that produce dust particles of very small diameter (known as fines). Dust



**Fig. 8.6** (a) Dust removal filter and (b) adsorption (activated carbon) filter (courtesy of Parker Hannifin – division Wilkerson).

removal filters are used to remove particulate material as small as  $0.5\mu\text{m}$  in the absence of liquid, thus including most microorganisms. They achieve 99.9999% particle removal efficiency, and are thus as successful as the equivalent coalescing filters.

#### *Adsorption (activated carbon) filters*

The compressed air passes through a large bed of activated carbon granules located either in an annular space or tubular section (Fig. 8.6(b)), and is stripped of oil vapour and organic pollutants (such as polycyclic aromatic hydrocarbons, VOCs and odorous substances), but both carbon monoxide and carbon dioxide remain. The activated carbon filters should always be preceded by a first stage general purpose filter and a second stage high-efficiency filter.

#### *Point-of-use filters*

As the air passes through distribution mains and branch lines, there is a possibility that cooling may occur. It is therefore preferable to install smaller individual filters as close as possible to the point at which the air is used, rather than relying on one large filter adjacent to the air receiver. These point-of-use filters must also remove particles that have accumulated during the distribution of compressed air: this can often occur, particularly in ageing large systems where rust and pipe scale can build up.

Point-of-use filters are generally used immediately before any tool, individual piece of equipment or sensitive food application that requires the removal of water and particulates greater than can be achieved using an after-filter. Since most water will be present at higher pressures, the point-of-use filters always should be installed upstream of any pressure-reducing valve.

If excessive condensate is present, a general purpose filter capable of removing bulk liquids and particulate matter as small as  $1\mu\text{m}$  should be installed as an initial filter to protect the second high-efficiency filter from bulk contamination. This high-efficiency coalescing filter can achieve 99.99% removal efficiency of  $0.01\mu\text{m}$  particulate matter. Alternatively, an activated carbon filter can be used as a second stage point-of-use filter: this should have the capacity to remove particulates that are too small to be removed by a coalescing filter. Both the coalescing and activated carbon filter can provide the required protection for the third stage sterile air filter. The general purpose filter can be omitted, resulting in a two stage point-of-use filter system.

#### *Sterile air filters*

It has been shown that compressed air lines can contain significant levels of bacteria and fungi, probably because the pipeline contains multiplication points for these microorganisms. It is generally accepted that filtration is

the most effective sterilization method for large volumes of compressed air. The filter should be installed as close as possible to the connection to the machine and there should be adequate facilities to allow steam sterilization of the filter. The piping between the sterile filter and the application must also be cleaned and sterilized on a regular basis. The following requirements apply for sterile air filters (Scott, 1998):

- They must be able to produce sterile compressed air under the typical usage conditions, including pulse flow, pressure drops, wet air or water in the system where the filter and associated air pipework are steam sterilized. The removal and flow characteristics may differ from those of a dry filter.
- They should be manufactured in full compliance with FDA requirements and accepted by the (USDA/FSIS) (Food Safety and Inspection Service) for use in federally inspected food plants. They must be constructed from inert food-grade materials that do not support bacteriological growth. A PTFE-impregnated depth filter or a non-shedding, hydrophobic membrane filter should be used.
- If a depth filter is used, it should be free of binder material, as this could act as a nutrient source for bacteria, allowing them to grow quickly enough to cause filter collapse. Filters with binder material are also more prone to rapid obstruction as the dirt-holding capacity of the media is reduced by the presence of the binder. The depth filter material must not allow preferential channelling (bypassing) of air as it passes through, as this will result in incomplete sterilization of the compressed air.
- Membrane filters feature membranes folded in a high surface area cylinder pleat pack held between stainless steel or polypropylene support screens, or may alternatively be designed as a hollow fibre construction. Filters made from hydrophobic (plasma-coated) PTFE have higher resistance in cleaning in place (CIP) processes and reduced differential pressure during drying after steam sterilization.
- To avoid the release of filter/fibre material or contaminant particles downstream of the system, the filter material should be encapsulated between perforated stainless steel cylinders of different diameter that are permanently bound to two stainless steel end caps by means of a high-temperature resistant epoxy sealant; alternatively, the filter material may be installed between inner and outer polypropylene support screens which can be permanently heat bonded to polypropylene end caps. This set up provides robust cartridges that are easily replaced.
- Filters should be small to allow for easy use, installation and maintenance.
- They should ensure maximum reliability over very long periods of time. An integrity test performed in situ on a regular basis can be used to verify that the filter is still capable of sterilizing the compressed air

stream. This test must be carried out by the manufacturer using a liquid or aerosol that contains a known microbial or particulate contaminant.

The filter housing must meet the following requirements:

- It should be manufactured from stainless steel, to allow steam or chemical sterilization of the filter and element. Steam sterilization is particularly appropriate if the compressed air comes into contact with microbiologically sensitive food.
- The air should flow from outside to inside, with the body seal, vent connection and drain connection of the housing located on the 'dirty' side of the process, to avoid the possibility of these components acting as sources of contamination. This ensures that there is only one critical seal between cartridge and housing.
- It must allow high flow rates and low pressure drop.
- Steam condensate must be removed correctly.
- It must be easy to maintain, and must allow appropriate access to seal rings for inspection.

#### *Exhaust filters*

An anti-bacterial exhaust filter can help to maintain a clean and hygienic processing environment. Cylindrical sterile filter cartridges can be used for sterile vent applications (CCFRA, 2005).

### **8.5.4 Dry air receiver**

The dry air receiver acts as an accumulator to support the operation of downstream applications that require large amounts of compressed air (several hundred m<sup>3</sup> per hour) in a short time frame. It must also prevent the over-rating of the dryers when sudden surges in air demand occur. The dry receiver should be installed at the outlet of the dust removal filter or activated carbon filter (which are both installed after the air dryer), and at the far reaches of the compressed air system, as required. The dry air receiver should always be installed upstream of the point-of-use or sterile filter.

### **8.5.5 Selection of the most suitable compressed air purification equipment**

The treatment method selected depends on the type of compressor used, and on the quality of compressed air (specified according to ISO8573-1:2010) required for the intended application. Table 8.8 offers some guidance in the selection of air treatment equipment. Preference should be given to third party validated purification equipment that is accompanied by a certificate guaranteeing that the targeted air quality will be attained.

**Table 8.8** Guidance in the selection of compressed air treatment devices

Type of air	Examples	Recommended equipment (with oil injected compressors)
Dry and pure air	General use, blow guns, simple robotics, air gauging, fine pneumatic tools, good factory air, conveying	Dryer, pre-filter & after-filter
Dry, pure and odour-free air	Blow moulding, air bearings, fluidic sensors, cosmetics, instrumentation, paint spraying, critical control air, food packaging and dairy production	Dryer, pre-filter, after-filter & activated carbon filter
Dry, pure and sterile air	Process contact air, pharmaceutical, hospital, food/beverage and dairy	Dryer, pre-filter, after-filter & activated carbon filter, sterile filter

Source: AMEI (2011).

## 8.6 Design and installation of compressed air distribution system

### 8.6.1 Hygienic design of the compressed air distribution network

The compressed air distribution network consists of the following:

- A main header that connects the compressor (in the compressor room) with the distribution system.
- A distribution header that distributes the compressed air within a consumption sector. This can be designed as a branch, or as a ring header with or without integrated branch lines.
- Connection branches (small distribution piping) that form the link between the distribution header and machines or points-of-use. The joint between the connection line and the distribution header should be at the top in order to prevent condensate being emitted along with the air.
- Connection equipment serves to connect the machines or points-of-use with the connection branches, and includes elements such as couplings, hoses and coils. It is at these points that large amounts of energy (in the form of compressed air) are wasted due to incorrect design.

The following guidance should be followed in the design of a hygienic compressed air distribution network:

- To reduce the possibility of condensation, the distribution piping should be kept short with the smallest possible number of bends and valves. Long radius bends and/or angled connections instead of 90° tees should be used. If there is a risk of the condensate freezing (leading to

deterioration of the compressed air flow and pressure drop), the air lines should be insulated or provided with specific heaters or heat tracing.

- When a compressed air tank is used to store compressed air, the piping should enter at the bottom of the receiver and exit from the top to mitigate moisture carryover.
- In compressed air systems 'vents at the high points are not required, but drains may be required at the low points. Drip legs should be installed at the bottom of risers, along with moisture trap mechanisms to remove that condensate. In moderate to severe sub-freezing temperatures these drip legs and traps should be heated to prevent freezing and pipe failure resulting from expansion of ice.
- Down loops should be avoided; if this is impossible, drain legs should be installed at the down loop. Blind loops and other locations that are likely to trap bacteria and favour proliferation should be avoided.
- The velocity in the main and distribution headers should be 6 m/s or less to prevent the air stream from carrying moisture and debris past drip legs, compromising condensate removal. The velocity should never exceed 9 m/s, as this is sufficient to transport any water and debris with the air stream past the drain legs. Line drops, feed lines or branch lines less than 15 m long work well at a velocity of 9 m/s, with the maximum recommended velocity being 15 m/s.
- Compressed air distribution piping should run from the most clean area towards the less clean areas. The compressed air system should deliver the compressed air first in the process area with the highest hygienic risk zone H and last in a low hygienic risk zone L.
- Lines transporting and supplying compressed air that will come into direct contact with food should not run close to or cross over with utilities that transport dirty fluids.
- Piping distributing compressed air should not run in cold areas such as cold- or frozen-storage warehouses, or in the vicinity of piping transporting chilled water, brine or refrigerant.
- The pipe must have adequate structural strength to support itself or be otherwise supported to prevent sagging. The support and design must also account for the sudden pressure swings and 'slamming' that can occur with valve actuation.
- Hangers in the system should not be tightly fastened to the pipe. Roller-type hangers work best with 10 cm or larger piping. Larger pipe hangers are also available that feature spring isolation between the truss contact and the hanger rod, minimizing the transfer of vibration and resonance to the structure of the building and downstream equipment.
- To minimize dead spots in which condensate may collect, distribution mains should be laid with at least 2% pitch in the direction of air flow so that gravity and air flow can carry the water to drain legs located at appropriate sites. The recommended distance between drain points is about 30 m.

- Point take-offs for compressed air should be piped off the top of compressed air manifolds (branches are taken from the upper side of the manifold) to mitigate the possibility of oil, debris and water contamination in the downstream compressed air distribution branches and to reduce the risk of these contaminants being passed into the process system or blown into the end-use device. Alternatively, the compressed air manifold may be run at low level, such that the branches have to rise towards the process equipment, draining any condensate back into the manifold.
- One drop line should be provided for each end-user, rather than connecting multiple end-users to the same drop line.
- On decoupling the push-pull connector, the compressed air supply line should be tightly sealed with a compression fitting. Air hoses should hang down without touching the floor; and hose ends should be protected with a plastic cover.
- Flexible connectors (used to correct misalignment) should not be used as they are prone to contamination. Moreover, any surplus pipework should be removed to eliminate dead-ends.

### 8.6.2 Valves

Valves in the compressed air system should meet the same hygienic requirements as those established for liquid-based systems. The components of the valve must be appropriate for the contaminants and air conditions found in any specific part of the system. Particular attention should be paid to the stem valve packing, seals and internal valve components. Some lubricants have a strongly corrosive effect on rubber components such as low nitrile Buna N, but Viton is suitable for use with most contaminants.

A check valve should be installed in the air piping downstream of the final filter to prevent backflow of product into the air pipeline. A check valve is not needed if the air piping enters the product zone from a point above the product overflow level which is open to the atmosphere or where dry materials are handled.

### 8.6.3 Construction materials to preserve the quality of the compressed air over the lifespan of the compressed air system

Air intake points and tubing should be constructed of smooth, durable, non-flaking material, such as plastic or stainless steel. Galvanized steel should not be used because the zinc top coating peels off over time. The piping that connects the compressor and the dryer, and the compressed air distribution network (main distribution header, branch distribution headers and small bore distribution piping) should be made of smooth, inert, non-corrosive and wear-resistant construction materials such as stainless steel. Stainless steel can withstand repeated sterilization by steam and a variety



of chemicals. Other suitable non-corrosive materials that can be used in the construction of small bore pipes are aluminium, copper and a number of plastic alternatives, but never carbon steel. Copper pipes can be used, and may inhibit the growth of bacteria, but they are generally limited to systems where the size of the bore pipe does not exceed 40mm. As with the air intake points and tubing, the small bore pipes should not be constructed from galvanized steel due to the risk of the zinc coating peeling off and contaminating the compressed air. Plastic piping is not suitable for use at or close to the compressor discharge for a number of reasons: it could release (outgas) volatile chemical components into the compressed air stream; it is subject to temperature restrictions; it could react with compressor fluids; and certain plastics (e.g. PVC) might shatter due to pressure or pulsation of the compressor. Materials used for pneumatic hoses and tubing and their connectors must be non-porous and resistant to hot water, steam and in particular to the cleaning and disinfection agents. The problem of outgassing must again be taken into consideration here. The external design of pneumatic hoses must be easy to clean (BCAS, 2007).

Welding is the preferred method for joining piping and components, with orbital welding of the stainless steel pipe providing the smoothest interior. Threaded connections are not recommended, even if sealants such as PTFE are used. Air piping resonates, with a high likelihood of leaking, and PTFE tapes and sealants have been found to break down when used in air piping. There is also strong evidence that particles from this type of material frequently enter downstream equipment and controls, particularly when sealed threads are used to connect dissimilar metals. More advanced pipe sealants can handle the resonance present in compressed air piping, but if the threads are not cleaned prior to the application of sealant, even this advanced type will not work properly. The sealant should be applied two to three threads back from the tip to avoid the migration of sealant into the system.

Piping, valves and fittings delivered to the job site should be capped and bagged to ensure that they remain clean. If a fitting becomes dirty prior to being installed, it should be cleaned before being incorporated into the system. Because contaminants may enter the piping during construction, the piping system must be flushed, cleaned and purged with compressed air before it is put into service. If gaskets and seals are used, problems with outgassing of elastomers may occur, which causes additional impurities in the gas piping system.

Intake, pre- and after-filters should have high mechanical and structural strength under operating conditions. Their construction must be robust enough to prevent the release of filter material. The body can be of stainless steel, sintered bronze, micro-fibre fleece or sintered plastic, or from other material that does not rust or corrode. Filter housings should be made of stainless steel with a bowl ideally made of transparent plastic so that the



filter bottom and the filter element can be monitored for the presence of abundant condensate and dirt. The dryer housings and wet receiver should be constructed from stainless steel or aluminium; coated steel is less suitable, while carbon steel should not be used at all.

## 8.7 Measures and procedures to prevent compressed air from contaminating the food processing area

### 8.7.1 Measures to prevent and reduce the bleeding of contaminated compressed air in the environment

Compressed air is commonly used as a means of lubricating pneumatic instruments but this practice requires powered pneumatic devices that are able to release or bleed compressed air into the atmosphere to ensure pressure differentials. Leakage or venting (bleeding) of lubricated compressed air is inherent to many devices, but results in the release of contaminants into the food environment, thereby contaminating exposed food. The following steps can reduce this contamination risk:

- Application of low-bleed pneumatic devices.
- Application of exhaust filters, with a general purpose filter (1  $\mu\text{m}$ ) upstream of a high-efficiency filter (0.01  $\mu\text{m}$ ) and an active carbon filter as third stage filter. The high-efficiency filter may remove 99.999% of all oil, and solid contaminants down to a particle size of 0.01  $\mu\text{m}$  or less. The carbon filter may then further reduce the oil content to less than 0.003 mg/m<sup>3</sup>. If required, additional sterile filtration can be carried out by means of a sterile filter.
- Venting of the instrument air away from open process containers or equipment.

### 8.7.2 Measures to prevent deliberate and unintentional leakage of compressed air

Leaks in the compressed air system and distribution piping should be avoided for several reasons:

- When compressed air is wasted, the compressor must compensate for the loss, thereby increasing the amount of energy consumed.
- Air distribution patterns may be disturbed, which is particularly detrimental in clean rooms.
- Compressed air leaking through pipes may contaminate the surrounding environment, creating unhygienic and unhealthy conditions.

The following steps should be taken to reduce leakage of air into the environment:

- situating the compressed air piping outside the food processing area;
- reducing the number of open blowing applications to a minimum;

- reducing the consumption of compressed air for blow-off applications, by applying air amplifiers that use a venturi action to draw in and mix significant amounts of ambient air into the air stream (ratios up to 25:1), in order to provide the required amount of air at the point-of-use;
- shutting off the compressed air to any application not in use;
- using air-tight pneumatic joints;
- fitting push–pull connectors with compression fittings;
- using methods such as (e.g. ultrasonic detection particularly valuable in noisy environments) to detect leaks and undertaking repairs rapidly when required;
- not using pressure increases to compensate for losses in air volume and pressure due to air leaks, because the higher the system pressure, the greater the leakage.

These preventive measures not only serve to prevent potential contamination of food, but also allow savings on energy and investments in the compressed air system.

## **8.8 Monitoring and maintenance of compressed air systems**

### **8.8.1 Monitoring of the compressed air system and the quality of the compressed air**

#### *Instruments to monitor the compressed air system*

The compressed air system must be provided with sensors that monitor and protect the compressor and all system components against any abnormal operating conditions, such as unusually high temperatures, extremes of pressure and other potentially damaging conditions. Flow, pressure and temperature indicators at strategic locations can provide an indication of correct functioning (trending) and can assist in diagnosing problems. Differential pressure gauges should be installed across pre- and after-filters to register increases in pressure drop, which indicate that cleaning or changing of the filter element is required.

#### *Monitoring the quality of the compressed air*

Sample taps should be installed to allow periodic monitoring of the air quality downstream of each pre-filter, dryer and after-filter (particulate and moisture), as well as at strategic locations throughout the system. Moisture and particles can enter the air system through leaks, meaning that periodic monitoring of the PDP and particle content in the compressed air at one or more locations downstream of the after-filters might prove advantageous.

- Dew point measurement is required in most production facilities for either refrigerated (4°C class) or desiccant (–40°C class or better) dryers. The key measurement points are the discharge air from each dryer, the lines to production areas and the air delivered to critical

**Table 8.9** Common dew point measurement probes

Sensor type	Characteristics	Field of application
Chilled mirror dew point monitors	<ul style="list-style-type: none"> <li>• Require diligent maintenance</li> <li>• Sensitive to dirt and air line contamination</li> <li>• Mirror requires frequent cleaning or replacement</li> </ul>	<ul style="list-style-type: none"> <li>• Laboratories</li> <li>• When any moisture in the product is catastrophic</li> </ul>
Aluminium oxide probes	<ul style="list-style-type: none"> <li>• High initial cost</li> <li>• Insensitive to dirt and debris</li> </ul>	<ul style="list-style-type: none"> <li>• Production facilities</li> </ul>
Ceramic probes	<ul style="list-style-type: none"> <li>• Lower initial cost</li> <li>• Less maintenance</li> <li>• Fast, accurate and reproducible response</li> <li>• Continued saturation may lead to deterioration</li> </ul>	
Thin film polymer sensor	<ul style="list-style-type: none"> <li>• High tolerance for corrosives</li> <li>• Immune to condensation</li> <li>• Long-term stability</li> <li>• Fast and accurate response</li> <li>• Low to moderate initial cost</li> <li>• Low accuracy in the lower PDP ranges</li> </ul>	<ul style="list-style-type: none"> <li>• Systems provided with a refrigerated dryer</li> </ul>

Source: Vaisala (2008).

applications. Although not every dew point monitor (Table 8.9) is suitable for every application, modern dew point probes offer solid performance with reduced sensitivity to installation conditions.

For sampling, the probe should be mounted upstream of the location where the PDP of the compressed air is to be monitored. A 6mm stainless steel sampling line should tap into the top half of the airline to protect the probe and sampling system from liquid water. Some systems include a filter either outside or inside the assembly. A flow meter should be installed to control the flow to the probe, while a pressure gauge must verify if the probe is seeing full line pressure. Because the dew point is a function of pressure, the air sample must be delivered to the probe at full line pressure. The sampling line should be sloped to drain condensate back into the header and should be as short as possible to prevent condensation in transit. Plastic and rubber sampling lines that absorb moisture and yield false dew point readings must be avoided.

- Particle measurement can be carried out using the same particle counting devices that are used to monitor the air quality in cleanrooms, with their design adapted to allow representative samples of compressed air to be taken.
- Fungal species and bacteria can be counted using a compressed gas sampler (cf. Chapter 16).

### 8.8.2 Maintenance and cleaning of the compressed air infrastructure

#### Maintenance

The following pieces of equipment require regular maintenance:

- **Filters** may corrode and become clogged (with dust or sludge), or a biofilm can form on the surface of the filter element. Filters can therefore be a potential source of contamination for the compressed air and require cleaning, maintenance or replacement if:
  - the differential pressure exceeds the maximum allowable pressure drop across the filter,
  - the filter integrity has been lost,
  - the filter is blocked (insufficient process airflow).

Maintenance is also required when:

- the filter reaches its expiry date,
- the manufacturer's stated cumulative steam life has been reached.

General purpose filters can be cleaned and reused, but in today's environment with labour costs high and spare parts expensive, the replacement of elements is often more economical. General purpose filters are usually changed before their pressure drop is greater than 0.5 bar. High-efficiency filter elements, which cannot be cleaned, must be replaced when a pressure drop of 0.7 bar indicates filter blockage, after 6000 working hours under normal working conditions or at least every 12 months. It is generally recommended that active carbon filters should be replaced after 1000–2000 hours operation at 21 °C. Because oil vapour has a characteristic odour, the installation of a small bleed valve downstream of the active carbon filter provides a means of checking whether any oil vapour is getting through the filter. An urgent change of the filter element is required if the typical oil vapour smell is observed. Air sterilization filters are sized to an initial pressure drop of 0.1 bar, but the replacement of these filters is not based on pressure drop increase; instead, filters are replaced after a defined number of steam sterilization cycles. After replacement, the filter housing and new filter must be re-sterilized *in situ*.

A filter housing with a transparent bowl ensures that the condensate and/or filter element can be easily observed, allowing rapid verification of correct functioning. Other indicators of a need to urgently replace the filter are changes in the liquid level or colour.

- **Dryers** should be properly operated and maintained. Drying media can be cleaned, regenerated or replaced. In deliquescent dryers the drying media must be replaced at least every 6 months, while regenerative desiccant material requires less frequent replacement.
- **Air lines** can be maintained without complete plant shut-down, because the installation of shut-off valves before all branches allow the isolation of specific branches from the main-distribution header.

- **Automatic drain traps** must be inspected periodically to ensure that they are not stuck in either the open or closed position. An automatic trap stuck in the open position will leak compressed air, while a trap stuck in the closed position will cause condensate to back-up and eventually be carried downstream where it can damage other system components or the process. For ease of inspection, the drain trap should be supported by a bypass line and valve so that the drain trap can be removed from service for maintenance while still allowing the supported component to remain in service.

### *Cleaning and disinfection*

The following parts of the compressed air system require frequent cleaning and disinfection:

- **Filters** can be disinfected by means of steam or a caustic solution at a high temperature. This should be around 80°C, but some synthetic filters may not withstand such high temperatures. Replacement is therefore the preferred option. If a disinfectant is used, it should be effective against the relevant microorganisms.
- **Air lines**, even those made of stainless steel pipe, will always contain a certain amount of installation dirt, which is introduced via valves and fittings, and dirt introduced when the line is opened to the atmosphere for maintenance. Cleaning the compressed air distribution system before starting disinfection is extremely important, because particles of dirt or groups of microorganisms can cause a shadowing effect.

Disinfection using food-grade saturated steam pressurized at 1 bar at a temperature of 121 °C allows the correct sterilization of the pipe work, filter and process. Any time the downstream pipe work or system is opened to the atmosphere, or when backflow of products from the process has occurred, re-sterilization is required. However, steam sterilization should ideally be before each critical process to ensure that the full system, including the compressed air pipe work and the filter are sterile before proceeding with the process. Decontamination using vapour containing hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>), ozone (O<sub>3</sub>) or chlorine dioxide (ClO<sub>2</sub>) is less common.

- **Automatic drain traps** should be removed once a month from their housing and cleaned in warm, soapy water (not solvents).

## **8.9 Hygiene control in the supply and application of food gases**

Numerous applications in the food industry rely on food gases, and the hygiene control of these gases is of utmost importance. Food packaging is

a typical example: this is usually the last step in the food processing chain, after which no further decontamination techniques are employed, meaning that high levels of hygiene are required for the process equipment, the process environment and the food gases. This section will examine contamination hazards related to the production, distribution, storage, supply and application of food gases and their derivatives and will discuss methods for avoiding contamination through proper hygienic design and risk control measures.

### **8.9.1 Application of food gases in the food industry**

A large number of gases are used in the food industry, as ingredients, food additives or process aids. They are used in many stages of the production process: in preparation, for example for carbonation and aeration; preservation, as in the application of liquid nitrogen or dry ice in freezing and chilling of food, or the regulation of pH using carbon dioxide; packaging such as modified atmospheric packaging (MAP) and the use of propane as propellant in whipped cream and vegetable oil pan spray; storage, for example nitrogen blanketing to avoid oxidative deterioration of processed vegetable oil; ripening, as in the use of ethylene to influence the ripening of fruit; pest control, such as the use of ethylene oxide and nitrogen to kill insects and vermin in cereals and grain-based products; cleaning such as blast cleaning using dry ice; disinfection, for example the treatment of water with chlorine, chlorine dioxide or ozone gas; and general purpose operations such as the mixing of liquids without the use of mechanical devices and the transportation/propulsion of liquids and solids from one site to another. They are also employed for safety reasons, such as the use of nitrogen during the handling of dry materials and the application of inflammable solvents to avoid fire risk (Nilsson *et al.*, 2004; Åkerlindh *et al.*, 2008).

Food gases are usually delivered by the supplier in a pressurized form (in gas cylinders, or in bulk road tankers used to fill local pressurized food gas storage tanks), a solid form (dry ice, in bulk or wrapped) or as a cryogenic liquid in cryogenic receptacles (thermally insulated vessels).

'Dry ice' is the term used for solid carbon dioxide that is available in large blocks, slices or small cylindrical pellets. These dry ice products are generally wrapped in plastic, paper or composite bags, and then stored and transported in insulated containers as secondary packaging. However, some products (particularly pellets) can also be supplied 'loose' in stainless steel or plastic containers, with no primary packaging. Dry ice is used to cool food products during transportation and to maintain the cold chain, without requiring direct contact with food. It is also used in direct contact with food to cool products such as meat and fish and to maintain the temperature during food mixing processes such as meat grinding. Liquid nitrogen ( $-196^{\circ}\text{C}$ ) is applied via cryogenic immersion or spray freezing of high-risk food products. In the former method, food products are conveyed through

a bath of liquid nitrogen, while the latter involves the spraying of liquid nitrogen onto the food while it is conveyed through the flash freezer. Nitrogen absorbs thermal energy from the product while changing phase from liquid to vapour.

### 8.9.2 EU regulations with regard to food gases

In the EU, according to the Miscellaneous Food Additives Regulations Directive 95/2/EC of 1995, packaging gases, propellants and gaseous preservatives are considered as food additives, and hence must meet the requirements of legislation relating to food safety. As such, packaging gases, propellants and gaseous preservatives must also comply with the Food Additives Labelling Regulations Directive 89/107/EEC, which requires that containers or cylinders containing food additives (including food gases) must be labelled with the name and E-number of all components, a statement 'suitable for use in food', a description of the storage conditions required, directions for use, a lot number and finally the name and address of the supplier. In Directives 95/2/EC and 2001/5/EC, E-numbers were established for carbon dioxide (E290), argon (E938), helium (E939), nitrogen (E941), nitrous oxide (E942), oxygen (E948), sulphur dioxide (E220) (permitted as a preservative/anti-oxidant in specified foods to specified levels) hydrogen (E949), and finally propane (E944), butane (E943a) and iso-butane (E943b) as propellants. Gases without E-numbers may not be used in contact with food.

Regulation (EC) No. 178/2002 requires that substances intended for use as a food should be traceable, starting from their status as raw material up to their final status as a food for consumption. Additives that remain present in a foodstuff for consumption must also satisfy the EU purity standards. No specific purity criteria relating to the use of food gases as ingredients have been established under EU law. The carbon dioxide used in carbonated beverages and the hydrogen used in the hydrogenation of fats are considered as ingredients, while the liquid nitrogen and dry ice used for cryogenic freezing purposes, and the gaseous carbon dioxide used for supercritical extraction are considered as process aids rather than food additives. Process aids are not currently classified as foods and are subject to very little legislation (British Compressed Gas Association, 2003; EIGA, 2011a).

In Europe, the food gases industry has adopted the HACCP concept to comply with Regulation (EC) No. 852/2004, judging the HACCP system to be the optimal method to:

- identify hazards of food contamination during food gas production;
- control, eliminate or reduce these food safety hazards;
- implement corrective actions;
- track out-of-control situations;
- monitor the result of the corrective actions that have been taken.

In the United States, the FDA and the USDA have also accepted the HACCP concept as a tool to control the quality of food gases. Regulation (EC) No. 852/2004 requires that processing aids also should be treated in a similar way to foods. However, they remain exempt from labelling regulations (EIGA, 2011a,b).

### **8.9.3 Hygienic and food-grade materials for the construction of equipment handling food gases, dry ice or liquid nitrogen**

#### *Construction materials for equipment used with pressurized food gases*

Because food gases are defined as food in Directive 95/2/EC, the Plastics and Materials in Contact with Food Regulations Directives 2002/16/EC and 2002/72/EC as well as Regulation (EC) No 1935/2004 must be taken into account during the construction of equipment for the production of food gases, in the selection of appropriate packaging, and during the storage and supply of food gases (British Compressed Gas Association, 2003; EIGA, 2006a).

Tanks, cylinders and other transportable containers should be designed using materials with an enhanced surface finish that renders them suitable for use in food. In most cases, carbon steel is used as material of construction for containers and storage tanks. Stainless steel ANSI 316L with a surface finish  $R_a \leq 0.8\mu\text{m}$  is recommended for use in food gas distribution systems, because it is compatible with food gases and does not introduce contaminants that would present a food safety risk. Because condensation may occur at the outside of the distribution piping, corrosion may take place from the outside to the inside of the piping if it is not constructed from stainless steel. As long as the food gases are kept in piping systems and pressure vessels made of impermeable materials such as steel, stainless steel or aluminium, they are effectively invulnerable, unless the distribution system has been exposed to the external environment for maintenance or repair.

Hoses and gaskets can pose a threat to gas quality due to the potential diffusion of contaminants such as humidity, and due to the contribution of chemical pollutants migrating from the plastic and rubber materials. Some gases may also break down or dry out plastic materials, rendering them porous. The number of hoses used should be kept to an absolute minimum; however, if they are essential, polypropylene is an excellent choice of material, as it is more gas tight than the alternatives and it can be welded (Åkerlindh *et al.*, 2008).

Gas cylinders are usually painted in accordance with the internationally recognized Gas Cylinder Identification – Part 3: colour coding (CSN EN 1089-3). Any painting should be completed before filling commences. During painting, the valve must be protected, because the interior of the gas cylinder and the valve must remain free from any external contamination. The European Industrial Gases Association (EIGA) has set



out recommendations for the colour coding (at the top of the cylinder) of transportable pure gas cylinder in the EN 1089-3: 2004 standard.

In certain situations, special attention should be paid to the materials used in the construction of the food processing/packaging equipment at the point at which the food gas is applied. Some gases, such as carbon dioxide, nitrous oxide and sulphur dioxide, become corrosive when wet. Wet food is commonly handled in the food industry, meaning that a corrosion-resistant material such as stainless steel AISI 316 should be used. This is the case, for example, in cryogenic freezers, where wet food becomes frozen using very cold carbon dioxide gas and dry ice (EIGA, 2008).

#### *Construction materials for equipment used with dry ice*

Equipment and containers used in the production, transport, storage, supply and application of dry ice must be constructed from materials that are easy to clean, resistant to corrosion, non-toxic and capable of withstanding a temperature of  $-78.4^{\circ}\text{C}$ . In the assembly of the food packaging or storage equipment at the point where the dry ice may become moistened, the use of stainless steel AISI 316(L) or better is recommended. At normal temperatures, solid carbon dioxide is compatible with most plastics and elastomers, but some non-ferrous and ferrous metals (such as carbon steel) become brittle at low temperatures and are very susceptible to fracture. Plastic materials should have an enhanced surface finish. The use of disposable plastic container liners should be considered as an option, especially for 'loose' products with no primary packaging. When the dry ice is wrapped, the potential for transfer of constituents from these plastic, paper or composite bags into the dry ice should be evaluated.

#### *Construction materials for equipment used with liquid nitrogen*

A cryogen such as liquid nitrogen is used to obtain very low temperatures. Liquid helium is not used in the food industry, as it is prohibitively expensive. Equipment, dewars and cryostats should be designed and manufactured using materials that offer high ductility even at cryogenic temperatures. For the production, storage and transfer of liquid nitrogen, equipment and containers can be manufactured from stainless steel that becomes stronger upon exposure to cold temperatures. Other materials suitable for use at temperatures down to  $-196^{\circ}\text{C}$  are aluminium, copper and copper alloys. 9% nickel steel is commonly used for large industrial tanks that need to withstand the low temperatures required for liquid nitrogen. Carbon steel, wrought iron, malleable iron, glass, rubbers, synthetic rubbers and plastics fail under stress at temperatures of between  $-20^{\circ}\text{C}$  and  $-60^{\circ}\text{C}$  due to brittle fracture, and are hence not suitable for use in cryogenic applications.

Stainless steel is the only appropriate material for tubing used to transfer cryogens. To prohibit condensation at the outside of the food gas distribution piping, the piping could be insulated. Rubber and plastic tubing

that become brittle and crack, should not be used. The liquid nitrogen that is spilled onto surrounding surfaces (such as flooring) as a result may then further damage the plastic coating on these surfaces.

#### **8.9.4 Hygienic production, storage, supply and application of pressurized food gases**

##### *Hygienic production of pressurized food gases*

Pressurized food gases must be produced according to the food quality standards described in IGC document 125/11/E of the European Industrial Gas Association, and according to the minimum specifications for food gas applications defined in EU Directives 96/77/EC, 2000/63/EC and 2002/82/EC and IGC Document 126/11/E. Because bulk gas production is carried out using closed, pressurized equipment for extended periods of time, the risk of environmental contamination (physical, chemical or microbiological) of the product is negligible (EIGA, 2011a,b).

Air used in the production of food gas should be drawn from one location and treated in the same way as air used in the production of compressed air (Sections 8.3 to 8.5). Before re-filling, each gas cylinder should be examined externally for dings, oil, grease and other signs of damage. The valve assembly should be examined for debris, oil or grease and should be cleaned if necessary. Any residual gas should be removed from the containers, which should then be purged, for example using a vacuum pump. Since filling gas cylinders with food gases does not expose the gases to the environment or plant workers, many of the practices used in typical food premises are not relevant in this case. Personal hygiene controls that would be necessary in high-risk environments are not required during filling; however, good hygiene practices should be in place during the maintenance of components and other items that will come into direct contact with the food gas. The food gas filling manifolds should be equipped with connections that correspond to the valve for that particular gas, to avoid accidental mixing of one gas for another and so that the correct gas cylinders can be attached to the manifold without the use of an adapter. During the filling process, the container valve must be checked for leakage using a leak detection solution, paying particular attention to glands. Soap is not recommended as a solution, because it can corrode the stem of the gas cylinder and leave residues. The leak detection solution is sprayed on and around the entire valve assembly. The appearance of bubbles in the solution indicates the presence of a leak. After filling, the tanks and cylinders must be fitted with anti-confusion couplings or alternative means of ensuring that cross-contamination does not occur. Finally, the supplier must check that no gas is escaping through the valve, after which that valve must be protected with a clean guard or dust cap (British Compressed Gas Association, 2003).

The food gas production and filling rooms must be designed in such a way that the area around the gas generator and filling installation can be

cleaned and that dirt does not accumulate. Regular floor sweeping and pest control are required to maintain the necessary conditions in these rooms.

*Hygienic storage of food gas cylinders and storage tanks*

Food gases must be transported in gas cylinders or bulk tanks that are reserved for the transport of food gases only, and must be clearly marked as such. Cylinders and containers containing compressed food gas must be secured against a wall or bench with a chain or belt (Fig. 8.7), or placed upright in a cylinder stand (cage or rack), to prevent them from being knocked over. For safety reasons, gas cylinders are commonly placed outside the factory building, ideally protected from the weather, under a shelter. If they are stored inside the factory, they should be placed in hygienically appropriate ventilated technical corridors or maintenance rooms, free from contaminants, heat and ignition sources. Gas detection is required for safety reasons. Gas cylinders should be stored in such a way as to prevent any



**Fig. 8.7** Cylinders and containers containing compressed food gas must be secured to prevent them from being knocked over (Parker Hannifin – division domnick hunter).

accumulation of debris that may provide a refuge for pests, and both these and bulk tanks should be situated close to the point-of-use. If the layout of the food factory makes the isolation of food gas cylinders in a technical room impossible, they should be placed in an enclosure with a 30° sloped roof close to the equipment in which the food gas is to be used.

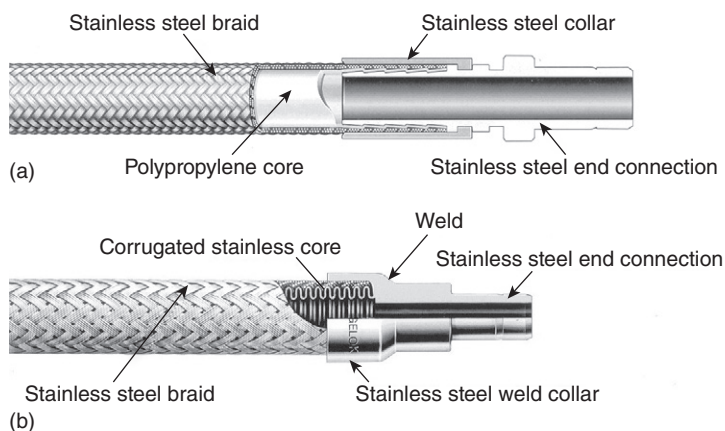
Each bulk gas storage tank should be used for only one gas. To prevent the wrong gas from being transferred into the tank, the storage tank and delivery tanker should have the same product-specific couplings for the transfer of that particular gas from the bulk gas carrier to the bulk gas storage tank. Prior to delivery, the hoses and piping used for bulk supply must be purged.

#### *Hygienic supply and application of pressurized food gases*

Process gases can be piped to the gas panels in the production area, or the food gas cylinders can be installed close to the connection to the machine. The process gas distribution system should be kept simple, without elbows or dead legs. Dead legs are places where non-circulating food gas or process air stagnates, and where water (which can sustain microbial growth) can accumulate. Food gas supply lines must also not sag and should be self-drainable towards water-traps. The food gas system (pipes, fittings, and filters) should be designed to allow wet cleaning or steaming if required. If pipework is used to feed food gas directly to the process, it should be manufactured from stainless steel and should be easy to clean *in situ*, especially if there is a risk of upward contamination of the pipe due to back-feeding. The design of the distribution system should include sampling points to verify the gas quality at critical points-of-use (Åkerlindh *et al.*, 2008).

For the supply of food gases, fixed, air-tight 316(L) stainless steel piping is recommended. Threaded piping should be avoided, because bacteria can adhere to the threads and proliferate. Clean welding is the ideal joining method, because mechanical methods such as flange fitting require special care to avoid offsets, gaps, penetrations and voids. Openings for connections on lines supplying food gases must be adequately protected from contamination. Shut-off valves such as globe valves should be used to prevent the unwanted supply of pressurized food gases into the process equipment, because the replacement of ambient air by gases such as nitrogen and carbon dioxide can lead to suffocation. Sufficient measures must always be taken to avoid blowing food supply gas into an open area, not only for reasons of operator safety but also for hygienic reasons, for example to avoid the disturbance of laminar air flow in cleanrooms.

Flexible connections are used to connect the process equipment with the pressurized food gas cylinder or the food gas supply line delivering food gas from a remote source. There are two groups: hoses composed of a plastic liner (polyamide, neoprene, polychlorotrifluoroethylene, nitrile rubber and PTFE) with metal or filament over-braiding, and hoses composed of a



**Fig. 8.8** Hoses with (a) a plastic liner and (b) a corrugated metallic liner.

corrugated metallic liner with over-braiding (Fig. 8.8). If plastic or rubber hoses are used, there is an increased risk of the migration of constituents into the supplied food gas and finally into the food product. At first glance, then, the stainless steel flex feed line seems to be the better option. However, the corrugations in the metallic liner are more prone to dirt accumulation, while rubber hoses with a plastic liner have a smooth and crevice-free bore ending with a hygienic end fitting. The transition from rubber hose to end fitting must be smooth with a minimal step in the bore.

As part of the maintenance programme for the facility, the food gas supply hoses should be regularly inspected for damage, deterioration and cleanliness, and must be maintained in good mechanical condition. The flexible hoses should be regularly cleaned in a washing area outside the production area to remove traces of oil, grease and particles. After cleaning, hoses and parts should be dried by purging with clean, dry, oil-free air or nitrogen. The hoses should be short and must not hang over open process equipment. Decoupled food gas supply hoses must be hung up without touching the floor, to ensure that the hose ends never drag on the ground and are therefore protected from contaminants by means of end caps or bags (CCFRA, 2005).

Ball lock quick connect couplings are used to facilitate the rapid connection or disconnection of food gas transfer hoses to or from fixed stainless steel food gas piping without the use of tools or special devices. These push–pull couplings allow the removal of mobile process equipment, thereby facilitating cleaning, maintenance and inspection of the whole process area. Quick couplings with automatic check valves eliminate dangerous gas spills, contributing to a safer working environment. The check valves also prevent the entry of contaminants into the hoses.



**Fig. 8.9** Flat surface quick coupling (courtesy of Gather Industrie GmbH).

A quick coupling consists of a female half (socket) and a male half (plug). Double shut-off couplings and flat face couplings, made of stainless steel, are recommended for the connection and disconnection of hoses in the food industry. These have a check valve in both the socket and plug and are used in systems where downstream spillage or contamination is undesirable. A special type of quick two-way shut-off coupling is the flat face coupling (Fig. 8.9), where the valve configuration prevents any loss of food gas on disconnection, as well as minimizing entry of contaminated air during connection. This push-pull connector with compression fitting is recommended for all applications where there is a risk of contamination of the food gas circuits, and to meet the safety, environmental protection and hygiene requirements of the work area.

To avoid physical harm to factory workers and conditions that could compromise food safety, food gas supply lines must be clearly labelled at regular intervals, especially when they cross multiple rooms, in order to indicate the contents of the pipe work and the direction of the flow of the gas. They should be marked with a coloured sticker bearing the name of the food gas to prevent the possibility of accidental switching of food gases. Food gas supply lines are often painted instead of labelled; however, paint can crack or flake, and some cleaning agents damage the physical integrity of the paint through chemical reaction. Painted surfaces that are cracked or flaked should be repainted immediately, but the best practice is to avoid painting entirely.

When MAP is employed, the connections of the gas supply installation to the packing machine should be clean and disinfected. The gases used in the MAP of solid food should be of high food grade quality, which means that they should have a purity and microbiological quality compatible with the product and process parameters. Before discharge of the food gas into the distribution lines, in-line cartridge filters of suitable quality must remove particles of 5  $\mu\text{m}$  or larger. Moisture may serve a growth medium for microbes, cause rapid pipe corrosion and deteriorate flow. Food gas must

be dried and sterile filtered (0.2 micron microbial retention filter) at their point-of-use. Filter design and materials of construction must be suitable for food contact use and sterilisation. Depending of the application and if absolute sterile conditions are required, a sterile filter can be used. Sensors should be installed to monitor the composition of the gas in the MAP equipment, with appropriate alarm systems in place if the supply of a particular food gas is inadequate (CCFRA, 2005; EIGA, 2011a).

Cylinders should not be emptied at a pressure below 2.5 bar; any lower, and there is a risk of the empty gas cylinders becoming contaminated with air. For that reason, full cylinders should not be connected to the same manifold as empty cylinders. Reverse flow can occur when an empty cylinder is attached to a pressurized system. In order to prevent the contamination of cylinders in service from either atmospheric sources or from back-feeding from the process, minimum pressure retention valves should be fitted to food gas cylinders, and check valves can be used in the supply system to prevent back flow of foreign matter or contaminants into the lines and empty gas cylinders.

### **8.9.5 Hygienic production, storage, supply and application of dry ice**

#### *Hygienic production of dry ice*

Dry ice is often added directly to high-risk foods such as raw meat and raw fish and is hence an important potential carrier of contamination. Dry ice may only be produced from liquid carbon dioxide that is certified as being suitable for use in foods. In the gases industry, it is the only solid product and one of the few that is not kept in a closed pressurized system. Directly or indirect physical contact occurs between the dry ice and the personnel employed in its manufacture, meaning that a more rigorous approach to safety and hygiene is required. The personnel working in the production area must wear clean and proper protective clothing, and must comply with good personal hygiene practices.

Equipment must be designed and manufactured to avoid dirt traps, with smooth surfaces free from pits, crevices and chips. Exposure of sections of the production line to airborne contamination should be reduced and entry of foreign bodies restricted, although for safety reasons CO<sub>2</sub> gases should be allowed to escape and access for maintenance and cleaning must be possible. Components that come into contact with food must be kept separate from potential contaminants, such as hydraulic fluid or lubricants. The packaging used for dry ice includes plastic bags, plastic film, paper and composite materials, such as plastic liners for bulk dry ice containers (EIGA, 2008), which must be made from food-compatible materials that are suitable for use at very low temperatures (−78.4°C). For safety reasons, the equipment for producing dry ice must not be hermetically closed. During the production of dry ice, CO<sub>2</sub>-gas is always formed and must be evacuated to the outside.



The 'Production, Storage, Transport and Supply of Gases for Use in Food', issued by the British Compressed Gas Association (2003) outlines the most important hygienic requirements for dry ice production environments: zoning within a hygienically designed factory; hygienically designed process, storage and supply equipment; separation of the food gases from any waste material and adequate waste removal practices; potable water for cleaning; sufficient drainage; adequate pest control system; sufficient air ventilation; use of food-grade lubricants; and sufficient lighting for proper working, cleaning and maintenance operations.

#### *Hygienic storage of dry ice*

Containers (full or empty) should be kept closed whenever possible. In open containers in which the temperature is much lower than the surrounding environment, moisture-laden air can be sucked in, contaminating the dry ice. However, dry ice should not be stored in a completely airtight container, because the sublimation of dry ice to carbon dioxide gas will cause the airtight container to expand and eventually explode. However, the rate of sublimation can be controlled and slowed down through the use of containers with sufficiently thick insulation.

Dry ice containers should not be used to store or transport non-foodstuffs unless appropriate cleaning procedures are implemented prior to the re-use of these containers for storing or transporting dry ice. Dry ice containers should be cleaned in a separate area away from where the dry ice is produced. Storage procedures should ensure that there is no potential for accumulation of debris that could provide a refuge for pests.

#### *Hygienic supply and application of dry ice*

Applications using dry ice require the opening of containers filled with 'loose' or wrapped dry ice, often involving manual handling. This imposes high hygienic demands on the operators working with dry ice that is intended to come directly or indirectly into contact with food, and requires high-quality room air (EIGA, 2008).

### **8.9.6 Hygienic production, storage, supply and application of liquid nitrogen**

#### *Hygienic production of liquid nitrogen*

Equipment for the production of nitrogen gas, and subsequently liquid nitrogen gas, operates in a completely closed mode for extended periods of time. This ensures that the risk of environmental contamination (physical, chemical or microbiological) of the product is negligible. The hygienic requirements for the production of nitrogen gas are the same as those that apply to the production of all compressed food gases, as described above. The equipment that converts nitrogen gas into its liquefied version also remains closed during the liquefaction process.



Dewars are filled with a filler line metal hose or via a connection with O-rings that make a gas-tight seal around the neck of the dewar. Prior to filling, the cryogenic container, and its inlet and outlet connections should be externally inspected for any signs of damage, oil, or grease. To avoid external contamination by reverse flow of environmental air into the dewar, the pressure inside the dewar should be slightly higher than atmospheric pressure.

#### *Hygienic storage of liquid nitrogen*

Liquid nitrogen can be stored in closed dewar vessels, from where it can be piped to the point-of-use, which is usually a cryogenic immersion or spray freezer. It is important to note that if the top cap or gas vent valve of a cryogenic vessel is left open, contaminated air can be sucked into the neck of the dewar. A loose fitting cap should protect the opening of the dewar to minimize the entry of air, which could hamper the food quality of the liquid nitrogen.

If the same containers are used to transport different food gases, effective cleaning of the containers between these loads is required to avoid contamination, and their cleanliness should be evaluated before they are returned to service. Containers that have been cleaned should be kept separate from those that have not.

#### *Hygienic supply and application of liquid nitrogen and liquid carbon dioxide in cryogenic freezers*

Stainless steel is the only material appropriate for the transfer of cryogens. The strainer in the liquid nitrogen supply line should be periodically checked for contamination. Cryogenic nitrogen is less contaminated than ambient air, both physically and microbiologically; it is important to remember, however, that maintenance activities can lead to contamination of the nitrogen or the freezer. The freezer should be frequently cleaned to maintain the quality of the food, with the required frequency depending on the type of food. When cryogenic liquids are exposed to the atmosphere, the cold boil-off gases condense the moisture in the air, creating a fog and possible condensation problems. It is important to remove all nitrogen vapour clouds quickly from the freezer through the use of an exhaust fan with sufficient capacity.

### **8.9.7 Management and maintenance of food gas quality and infrastructure**

#### *Contamination hazards during the distribution of food gases*

If piping that supplies food gases passes through rooms with perceptibly higher concentrations of impurities in the air, i.e. with a partial pressure higher than that inside the systems, it is important to note that even small leaks in the system are a potential source of contamination due to diffusion.

Another risk is the injector effect, where a gas passing a leak at high speed can cause a vacuum, introducing ambient air into the system. Regular leak tests should therefore be carried out on gas supply systems. The most commonly identified pollutants at the distribution stage are water, particles, hydrocarbons and microorganisms (Nilsson *et al.*, 2004; Åkerlindh *et al.*, 2008).

- The presence of water in process gases is highly significant, because it is the basis for the growth of microorganisms. Although gases are usually distributed at pressures six to eight times the ambient air pressure, the water vapour pressure in ambient air is higher than that in a system containing a dry gas. This may allow the moisture to diffuse inwards through the weaker components of the system, such as hoses and other non-metallic components. The moisture content in the gas can be monitored at the supply unit, after the dryers or the main tank, and at the points-of-use. Any difference between sample points in terms of water vapour content could be due to leaks or inward diffusion through poorly sealed joints. The food gas distribution system can be dried out by purging or flushing with dry gas.
- In older systems made of galvanized steel or copper piping, corrosion is also a major contributor to contamination, not least because the initial particles can act as an abrasive, grinding off more particles from the pipe wall. Opening the distribution system exposes the system to particles from the external environment; alternatively, dust or dirt may enter the system accidentally as a result of the gas cylinders being incorrectly mounted or connected. Although these foreign bodies can be caught in the point-of-use filters, it is preferable to catch them further upstream of the process using traps and inline filters (inert plastic cartridges installed in a stainless steel housing). Furthermore, immediately after maintenance and repairs, the piping system should be flushed prior to use. As part of the maintenance and surveillance programme, the pressure difference over the filters should be continuously monitored, and the integrity of the filters should be tested by sampling the particle content of the gas before using the system.
- Hydrocarbon impurities can originate from malfunctioning oil-lubricated compressors, chemical pollutants migrating from the plastic and rubber materials, and pipework and components that are not properly cleaned before installation. In addition, air contaminated with hydrocarbons may be entrained within the gas piping via leaks or via the intake of air used in the production of a certain food gas, which can also result in hydrocarbon impurities.
- The bioburden of the gases being used also must be taken into account, especially in sterile manufacturing facilities. Microbial growth requires the presence of water (condensed or as vapour) and/or nutrition (such as hydrocarbons). To rule out the presence of microorganisms,

point-of-use sterile filters (0,2 µm filters, in the case of aseptic applications) should be used. These must be regularly changed and tested for integrity.

#### *Managing the quality of food gases*

Several national and international authorities require that food manufacturers have a supplier control system in place. Hence, the supplier of the food gas should have a food safety management system (e.g., FS 22000) in place, that is checked by a certification organization. This food safety management system should cover the complete chain of purification and distribution of the food gas. A risk analysis should be made, and the necessary measures should be implemented to prevent contamination of the food gases produced. The supplier is required to have documented production procedures, proper analytical methods and equipment, as well as a quality system including procedures on how changes are managed and announced to customers. Additional in-house testing at the customers site is not required.

The food gas should be purchased according to an agreed specification, should always be delivered with a Certificate of Conformity or a Certificate of Analysis, and should be traceable. A Certificate of Conformity states that the supplied product meets minimal purity specifications, but does not offer analytical results. A typical Certificate of Analysis states the minimal product specification, along with the results of a specific analysis of the batch.

#### *Cleaning and maintenance of the pressurized food gas, dry ice and liquid nitrogen infrastructure*

Equipment used in the manufacture of food gas should be cleaned prior to first use and again if exposed to a contaminant, such as after intrusive maintenance and repair. However, physical entry into the food gas production system should be kept to a minimum and avoided where possible.

The hygiene of the food gas distribution piping must be maintained, for example through the use of steam sterilization. Sterile filters should be sterilized in counter-flow after each batch to avoid clogging. The filter in the gas supply line should be changed when filter integrity is lost, when filter blockage leads to insufficient process gas flow, when the manufacturer's stated cumulative steam life has been reached or when planned maintenance indicates a filter change is required.

### **8.9.8 Safe handling of food gases, dry ice and liquid nitrogen**

Compressed food gases, dry ice and liquid nitrogen should always be handled and securely stored in a cool, dry and well-ventilated area. They should be kept away from busy or heavily used parts of the plant, emergency exits, electrical apparatus, heat sources, sparks and flames. Vessels, receptacles and piping containing cryogenic nitrogen or dry ice should never be touched, in order to avoid severe cold burns. Gloves are required to protect the

hands, as well as clear plastic goggles with side protection to prevent eye damage. Because the ambient air and hence oxygen can be replaced by the food gas being used, potentially leading to suffocation, wall-mounted oxygen deficiency monitors should be installed to continually monitor the oxygen levels in the atmosphere.

## 8.10 Conclusion

In this chapter, the reader got a better view on the contaminants that may be present in compressed air due to poor design and malfunctioning of the compressed air system. Measures should be taken to prevent the entry and generation of these contaminants in the compressed air system, and the appropriate equipment should be available to remove these unwanted substances. The quality of the compressed air should be monitored continuously to detect off-normal operating conditions of both the compressor or air purification equipment. When the produced and treated compressed air is out of specification, cleaning, disinfection, maintenance, repair or, in a worse case, re-design or replacement of components in the compressed air system may be required.

Food gases, dry ice and liquid nitrogen are often used at the end of the food processing chain after which no further decontamination techniques are applied. Due to the differences in the nature (physical state) of pressurized food gases, dry ice and liquid nitrogen the conditions and equipment used to hygienically produce, store, supply and apply these substances are quite different.

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# Cleaning and disinfection practices in food processing

J. T. Holah, Campden BRI, UK

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**Abstract:** With respect to food and operative safety, cleaning and disinfection (sanitation) ranges from the cosmetic, through good housekeeping and the prevention of slips and trips, to maintaining the quality control of subsequent product batches and to the absolute practical measures for controlling the cross-contamination of allergens and pathogenic microorganisms. As such, the hazard(s) that the sanitation programme is designed to control must be understood and the greater the risk of the hazard(s), the more thought is required as to the programme's design and management. This chapter reviews the principles of sanitation including sanitation methods, procedures and chemicals, and the management of sanitation including cleaning schedules, validation, monitoring and verification of sanitation programme performance and management responsibilities. Whilst much of this is traditional, new knowledge is now available to help control the risk of pathogens and allergens, driven by the increase in the availability of ready-to-eat (RTE) chilled and dry food products.

**Key words:** sanitation, cleaning, disinfectant, biofilms, water, surfactants, alkalis, acids, sequestrants, disinfectant testing, wholeroom disinfection, cleaning schedules, periodic cleaning, monitoring, verification, environmental sampling.

## 9.1 Introduction

Provided that the process environment and production equipment have been hygienically designed (Chapters 3 and 4), cleaning and disinfection (referred to together as *sanitation*) are the major day-to-day controls of the hard surface vectors of food product contamination and, if effective, can reduce hazards (microorganisms, allergens, foreign bodies) within the processing environment. When undertaken correctly, sanitation programmes have been shown to be cost-effective and easy to manage, and, if diligently applied, can both reduce the risk of hazards and maintain the organoleptic

properties of the food product, whilst maintaining a safe working environment for food operatives. Given the intrinsic demand for high standards of hygiene, particularly in ready-to-eat (RTE) foods, together with pressure from customers, consumers and legislation for ever-increasing hygiene standards, sanitation demands the same degree of attention as any other key process in the manufacture of safe and wholesome foods.

This chapter is concerned with the sanitation of 'hard' surfaces only – equipment, floors, walls and utensils – as other surfaces, e.g. protective clothing or skin, will be dealt with under personal hygiene (Chapter 12). In this context, surface sanitation is undertaken to:

- remove food soils, including allergens, that would be detrimental to the safety or organoleptic quality of subsequent production runs;
- remove microorganisms, or material conducive to microbial growth, which reduces the chance of contamination by pathogens and, by reducing spoilage organisms, may extend the shelf-life of some products; it may also provide an effective microbiological control break between production batches;
- remove materials that could lead to foreign body contamination or could provide food or shelter for pests;
- extend the life of, and prevent damage to, equipment and services, provide a safe and clean working environment for employees and boost morale and productivity;
- maintain plant operating parameters during food processing, including heat transfer and flow parameters;
- present a favourable image to customers and the public – on audit, the initial perception of an 'untidy' or 'dirty' processing area, and hence a 'poorly managed operation' is subsequently difficult to overcome.

## 9.2 Sanitation principles

Sanitation is undertaken primarily to remove all undesirable material (food residues, microorganisms, foreign bodies and cleaning chemicals) from surfaces in an economical manner, to a level at which any residues remaining are of minimal risk to the quality or safety of the product. Such undesirable material, generally referred to as 'soil', can be derived from normal production, spillages, line-jams, equipment breakdown, equipment maintenance, packaging or general environmental contamination (dust and dirt). To undertake an adequate and economic sanitation programme, it is essential to characterise the nature of the soil to be removed.

Product residues on surfaces are easily observed and may be characterised by their chemical composition, e.g. carbohydrate, fat or protein. It is also important to be aware of processing and/or environmental factors, however, as the same product soil may lead to a variety of cleaning problems,

depending primarily on moisture levels and temperature. Generally, the higher the product soil temperature (especially if the soil has been baked) and the greater the time period before the sanitation programme is initiated (i.e. the drier the soil becomes), the more difficult the soil is to remove.

With respect to microorganisms on food production surfaces, the food industry has always recognised that they are present (either within the surface soil or attached to the surface) and that their numbers increase during production and are reduced by cleaning and disinfection. Initially it was considered that microorganisms adhered to the food product contact surfaces could be an important source of potential contamination leading to serious hygienic problems and economic losses due to food spoilage. For example, pseudomonads and many other Gram negative organisms detected on surfaces are the (spoilage) microorganisms of concern in chilled RTE foods. Since this time, however, we have recognised that food contact surfaces can give rise to biofilms, can support the growth of pathogens, and more recently, that food processing environments will develop their own persistent 'house' flora, some of which can be pathogenic.

There are a number of factors that have been shown to affect attachment and biofilm formation such as the level and type of microorganisms present, surface conditioning layer, substratum nature and roughness, temperature, pH, nutrient availability and time available. Several reviews of biofilm formation in the food industry have been published including Pontefract (1991), Holah and Kearney (1992), Mattila-Sandholm and Wirtanen (1992), Carpentier and Cerf (1993), Zottola and Sasahara (1994), Gibson *et al.* (1995) and Kumar and Anand (1998). In general, however, biofilm formation may be found on environmental (particularly drains) and some production (e.g. flumes and cooling canals) surfaces and the growth of attached cells through micro-colonies to extensive biofilms is only limited by regular cleaning and disinfection. Indeed, following hazard analysis and critical control point (HACCP) principles, if the food processor believes that biofilms are a risk to the safety of the food product, appropriate control steps (e.g. cleaning and disinfection) must be taken, validated, monitored and verified.

Much of our knowledge about the growth and persistence of microorganisms has been gained following concerns about *Listeria monocytogenes* in the chilled RTE industry. Following the first incidents associated with *Listeria* in chilled foods in the late 1980s, a number of authors have isolated *Listeria monocytogenes* from a range of food processing surfaces (Walker *et al.*, 1991; Lawrence and Gilmore, 1995; Destro *et al.*, 1996). Evidence for *L. monocytogenes* strain persistence within factory processing areas has been demonstrated for 8 months (Rørvik *et al.*, 1995), 11 months (McLauchlin *et al.*, 1990), 14 months (Johansson *et al.*, 1999), 1 year (Lawrence and Gilmour, 1995), 17 months (Pourshaban *et al.*, 2000), 2 years (McLauchlin *et al.*, 1991), 3 years (Brett *et al.*, 1998, Holah *et al.*, 2004), 40 months (Unnerstad *et al.*, 1996), 4 years (Nesbakken *et al.*, 1996, Aase



*et al.*, 2000; Fonnesbech Vogel *et al.*, 2001), 7 years (Unnerstad *et al.*, 1996; Miettinen *et al.*, 1999) and 10 years (Kathariou, 2003). The nature of strain persistence is unknown but may be due to a number of factors affecting biological/physiological adaptation (surface attachment, biofilm formation, attachment strength, reduced growth rate, quiescence, cleaning and disinfection resistance) to the whole range of environmental conditions typical in chilled food factory environments (low temperature, wide pH range, fluctuating nutrient supply and moisture levels, frequency of cleaning and disinfection, etc.). Lundén *et al.* (2003a, 2003b) have demonstrated that persistent strains may show enhanced surface adherence and increased disinfection resistance at very low disinfectant concentrations, though Holah *et al.* (2002) found no evidence of disinfection resistance of certain persistent strains to disinfectants at their normal in-use concentration.

*Salmonella* contamination incidents in the late 2000s in, for example, chocolate, dried milk powder, peanut butter and cereals has also focused our attention on this organism, particularly in dry food processing operations where dry cleaning techniques predominate. In one cereal manufacturer, *Salmonella* Agona was isolated from a production plant and product in 1998 and then the same strain was isolated in 2008 (Centres for Disease Control and Prevention, 2008), suggesting potential pathogen survival or persistence in dry environments also.

Within the sanitation programme, the cleaning phase can be divided up into three sections, following the pioneering work of Jennings (1965) and interpreted by Koopal (1985), with the addition of a fourth stage to cover disinfection. These are described below:

1. The wetting and penetration by the cleaning solution of the soil and to the equipment surface.
2. The reaction of the cleaning solution with both the soil and the surface to facilitate: peptisation of organic materials, dissolution of soluble organics and minerals, emulsification of fats and the dispersion and removal from the surface of solid soil components.
3. The prevention of re-deposition of the dispersed soil back onto the cleaned surface.
4. Disinfection solution contact with residual microorganisms to facilitate reaction with cell membranes and/or penetration of the microbial cell to produce a biocidal or biostatic action. Depending on whether the disinfectant contains a surfactant and the disinfectant practice chosen (i.e. with or without rinsing); this may be followed by dispersion of the microorganisms from the surface.

To undertake these four stages, sanitation programmes employ a combination of four major factors as described below. The combination of these four factors varies for different cleaning systems and, generally, if the use of one energy source is restricted, this shortfall may be compensated for by utilising greater inputs from the others:

- mechanical or kinetic energy;
- chemical energy;
- temperature or thermal energy;
- time.

Mechanical or kinetic energy is used to physically remove soils and may include scraping, manual brushing and automated scrubbing (physical abrasion) and pressure jet washing (fluid abrasion). Of all four factors, physical abrasion is regarded as the most efficient in terms of energy transfer (Offiler, 1990), and the efficiency of fluid abrasion and the effect of impact pressure has been described by Anon. (1973), Holah (1991) and Burfoot *et al.* (2009). Mechanical energy has also been demonstrated to be the most efficient for biofilm (Blenkinsopp and Costerton, 1991; Mattila-Sandholm and Wirtanen, 1992; Wirtanen and Mattila-Sandholm, 1993, 1994; Gibson *et al.*, 1999).

In cleaning, chemical energy is used to break down soils to render them easier to remove and to suspend them in solution to aid rinsability. At the time of writing, no cleaning chemical has been marketed with the benefit of aiding microorganism removal. In chemical disinfection, chemicals react with microorganisms remaining on surfaces after cleaning to reduce their viability. The chemical effects of cleaning and disinfection increase with temperature in a linear relationship and approximately double for every 10°C rise. For fatty and oily soils, temperatures above their melting point are used, to break down and emulsify these deposits and so aid removal. The influence of detergency in cleaning and disinfection has been described by Dunsmore (1981), Shupe *et al.* (1982), Mabesa *et al.* (1982), Anderson *et al.* (1985) and Middlemiss *et al.* (1985).

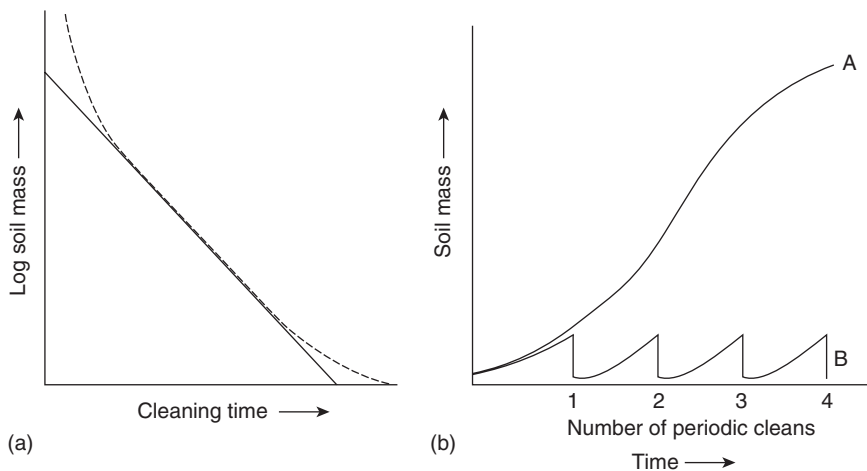
For cleaning processes using mechanical, chemical and thermal energies, generally the longer the time period employed, the more efficient the process. When extended time periods can be employed in sanitation programmes, e.g. soak-tank operations, other energy inputs can be reduced (e.g. reduced detergent concentration, lower temperature or less mechanical brushing).

Soiling of surfaces is a natural process which reduces the free energy of the system. To implement a sanitation programme, therefore, energy must be added to the soil to reduce both soil particle–soil particle and soil particle–equipment surface interactions. The mechanics and kinetics of these interactions have been discussed by a number of authors (Jennings, 1965; Schlusser, 1975; Loncin, 1977; Corrieu, 1981; Koopal, 1985; Bergman and Tragardh, 1990), and readers are directed to these articles since they fall beyond the scope of this chapter. Research continues on the theoretical aspects of soil removal to gain a better understanding of the relative importance of both the physical and chemical removal factors and the relative influence of soil to soil and soil to surface bonding mechanisms. A useful review of these factors was undertaken by Fryer and Christian (2005)

who have characterised soil removal in terms of deposit thinning (weaker soil to soil bonding) and deposit removal in large ‘chunks’ (weaker soil to surface bonding) for tomato and milk deposits. Suffice to say that it will be many years before soil removal mechanisms can be predicted for all soil types and that practical factory-based cleaning trials to optimise cleaning will still predominate.

In practical terms, however, it is worth looking at the principles involved in basic soil removal, as they have an influence on the management of sanitation programmes. Soil removal from surfaces decreases such that the log of the mass of soil remaining per unit area is linear with respect to cleaning time (Fig. 9.1(a)) and thus follows first order reaction (log linear) kinetics (Jennings, 1965; Schlusser, 1975). This approximation, however, is not valid at the start and end of the cleaning process and, in practice, soil removal is initially faster and ultimately slower (dotted line in Fig. 9.1(a)) than a first order reaction predicts. The reasons for this are unclear, though initially, non-adhered, gross soil is usually easily removed (Loncin, 1977) whilst ultimately, soils held within surface imperfections, bound to surfaces or otherwise protected from cleaning effects, is more difficult to remove (Holah and Thorpe, 1990).

Routine cleaning operations are never 100% efficient, and over a course of multiple soiling/cleaning cycles, soil deposits (potentially including microorganisms) will be retained. As soil accumulates, cleaning efficiency will decrease and, as shown in plot A, Fig. 9.1(b), soil deposits may for a period increase exponentially. The timescale for such soil build-up will differ between processing applications and can range from hours (e.g. heat



**Fig. 9.1** Soil removal and accumulation. (a) Removal of soil with cleaning time. Solid line is theoretical removal; dotted line is cleaning in practice. (b) Build-up of soil (and/or microorganisms); A, without periodic cleans and B, with periodic cleans (after Dunsmore *et al.*, 1981).

exchangers) to typically several days or weeks, and in practice can be controlled by the application of a 'periodic' clean (Dunsmore *et al.*, 1981). Periodic cleans are employed to return the surface-bound soil accumulation to an acceptable base level (plot B, Fig. 9.1(b)) and are achieved by increasing cleaning time and/or energy input, e.g. higher temperatures, alternative chemicals (such as a periodic acid de-scale, when alkaline cleaning agents are used routinely) or manual scrubbing. A typical example of a periodic clean is the 'weekend clean-down'.

### 9.3 Cleaning chemicals

In many instances, management view the costs of sanitation as the price of the chemicals purchased, primarily because this is the only 'invoice' that they see. In reality, however, sanitation chemicals are likely to represent approximately only 5% of the true costs, with labour, energy and water costs being the most significant. The purchase of a good quality formulated cleaning product, whilst being initially more expensive, will more than cover its costs by increasing both the standard of clean and cleaning efficiency.

Within the sanitation programme it has traditionally been recognised that cleaning is responsible for the removal of not only the soil but also the majority of the microorganisms present. Mrozek (1982) showed a reduction in bacterial numbers on surfaces by up to 3 log orders whilst Schmidt and Cremling (1981) described reductions of 2–6 log orders. The results of work at Campden BRI on the assessment of well-constructed and competently undertaken sanitation programmes on food processing equipment in ten chilled food factories is shown in Table 9.1. The results suggest that both cleaning and disinfection are equally responsible for reducing the levels of adhered microorganisms and suggest a combined 3–4 log reduction of microorganisms. Indeed, sanitation can be seen as a unit process with both cleaning and disinfection actively involved in reducing microbial levels. For example, if the starting level of microorganisms is  $10^7$  per unit area, a sanitation programme may result in a count after sanitation of  $10^3$ . For a starting figure of  $10^6$ , this may be  $10^2$  following sanitation, etc. It is important, therefore, not only to purchase quality cleaning chemicals for their soil removal capabilities but also for their potential for microbial removal.

**Table 9.1** Arithmetic and mean log bacterial counts (per swab) on food processing equipment before and after cleaning and after disinfection

	Before cleaning	After cleaning	After disinfection
Arithmetic mean	$7.41 \times 10^7$	$4.48 \times 10^5$	$1.80 \times 10^3$
Log mean	4.73	2.79	1.30
No. of observations	480	798	2400

Unfortunately no single cleaning agent is able to perform all the functions necessary to facilitate a successful cleaning programme; so a cleaning solution, or detergent, is blended from a range of typical characteristic components:

- water;
- surfactants;
- inorganic alkalis;
- inorganic and organic acids;
- sequestering agents.

For the majority of food processing operations it may be necessary, therefore, to employ different cleaning products, for specific operations. This requirement must be balanced by the desire to keep the range of cleaning chemicals on site to a minimum so as to reduce the risk of using the wrong product, to simplify the job of the safety officer and to allow chemical purchase to be based more on the economics of bulk quantities. The range of chemicals and their functions is historical and well documented (Elliot, 1980; ICMSF, 1980, 1988; Russell *et al.*, 1982; Hayes, 1985; Koopal, 1985; Anon., 1991; Holah, 1991) and has changed little since these reviews; only an overview of the principles is given here.

Water is the base ingredient of all 'wet' cleaning systems and should be of potable quality, particularly with respect to microorganism levels. Water provides the cheapest, readily available transport medium for rinsing and dispersing soils, has dissolving powers to remove ionic-soluble compounds such as salts and sugars, will help solubilise proteins below their coagulation point, emulsify fats at temperatures above their melting point, and, in high pressure cleaning, can be used as an abrasive agent. On its own, however, water is a poor 'wetting' agent and cannot dissolve non-ionic compounds.

Organic surfactants (surface-active or wetting agents which react physically with food soils) are amphipolar and are composed of a long non-polar (hydrophobic or lyophilic) chain or tail and a polar (hydrophilic or lyophobic) head. Surfactants are classified as anionic (including the traditional soaps), cationic or non-ionic, depending on their ionic charge in solution, with anionics and non-ionics being the most common. Amphipolar molecules aid cleaning by reducing the surface tension of water and by emulsification of fats. If a surfactant is added to a drop of water on a surface, the polar heads disrupt the water's hydrogen bonding and so reduce the surface tension of the water and allow the drop to collapse and 'wet' the surface. Increased wettability leads to enhanced penetration into soils and surface irregularities and hence aids cleaning action. Fats and oils are emulsified as the hydrophilic heads of the surfactant molecules dissolve in the water whilst the hydrophobic end dissolves in the fat. If the fat is surface-bound, the forces acting on the fat/water interface are such that the fat particle will form a sphere (to obtain the lowest surface area for its given

volume), causing the fat deposit to 'roll-up' and detach itself from the surface.

Alkalis and acids react chemically with food soils. Alkalis are useful cleaning agents as they are cheap, break down proteins through the action of hydroxyl ions, saponify fats and, at higher concentrations, may be bactericidal. Strong alkalis, usually sodium hydroxide (or caustic soda), exhibit a high degree of saponification and protein disruption, though they are corrosive and hazardous to operatives. Correspondingly, weak alkalis are less hazardous but also less effective. Alkaline detergents may be chlorinated to aid the removal of proteinaceous deposits, but chlorine at alkaline pH is not an effective biocide. The main disadvantages of alkalis are their potential to precipitate hard water ions, the formation of scums with soaps, and their poor rinsability. It is currently not known whether alkaline cleaning agents modify allergenic protein residues sufficiently to reduce or eliminate their allergenicity.

Acids (e.g. nitric) have low detergency, although they are very useful in solubilising carbonate and mineral scales, including hard water salts and proteinaceous deposits. As with alkalis, the stronger the acid the more effective it is; though, in addition, the more corrosive to plant and operatives. Acids are not used as frequently as alkalis in food operations and tend to be used for periodic cleans.

Sequestering agents (sequestrants or chelating agents) are employed to prevent mineral ions precipitating by forming soluble complexes with them. Their primary use is in the control of water hardness ions and they are added to surfactants to aid their dispersion capacity and rinsability. Sequestrants are most commonly based on ethylene diamine tetracetic acid (EDTA), which is expensive. Although cheaper alternatives are available, these are usually polyphosphates which are environmentally unfriendly.

A general purpose food detergent may, therefore, contain a strong alkali to saponify fats, weaker alkali 'builders' or 'bulking' agents, surfactants to improve wetting, dispersion and rinsability and sequestrants to control hard water ions. In addition, the detergent should ideally be safe, non-tainting, non-corrosive, stable, environmentally friendly and cheap. The choice of cleaning agent will depend on the soil to be removed and on its solubility characteristics and these are summarised for a range of chilled products in Table 9.2 (modified from Elliot, 1980).

Because of the wide range of food soils likely to be encountered and the influence of the food manufacturing site (temperature, humidity, type of equipment, time before cleaning, etc.); there are currently no recognised laboratory methods for assessing the efficacy of cleaning compounds. Food manufacturers have to be satisfied that cleaning chemicals are working appropriately, therefore, by conducting suitable field-based, validation trials. Because of their key role in the sanitation process, therefore, food manufacturers should only purchase high-quality detergents: cost cutting

**Table 9.2** Solubility characteristics and cleaning procedures recommended for a range of soil types

Soil type	Solubility characteristics	Cleaning agent recommended
Sugars, organic acids, salt	Water soluble	Mildly alkaline detergent
High-protein foods (meat, poultry, fish)	Water soluble Alkali soluble Slightly acid soluble	Chlorinated alkaline detergent
Starchy foods, tomatoes, fruits	Partly water soluble Alkali soluble	Mildly alkaline detergent
Fatty foods (fat, butter, margarine, oils)	Water insoluble Alkaline soluble	Mildly alkaline detergent; if ineffective, use strong alkali
Heat-precipitated water hardness, milk stone, protein scale	Water insoluble Alkaline insoluble Acid soluble	Acid cleaner, used on a periodic basis

Source: Modified from Elliot (1980).

for less-effective chemicals may seriously affect the efficacy of the sanitation process.

## 9.4 Disinfectants

Although the majority of the microbial contamination is removed by the cleaning phase of the sanitation programme, there may be sufficient viable microorganisms remaining on the surface to warrant the application of a disinfectant. The aim of disinfection is therefore to further reduce the surface population of viable microorganisms, via removal or destruction, and/or to prevent surface microbial growth during the inter-production period.

Elevated temperature is the best disinfectant as it penetrates into surfaces, is non-corrosive, is non-selective to microbial types, is easily measured and leaves no residue (Jennings, 1965). For specialist, periodic applications, heat can be used in a controlled fashion, for example:

- The use of naked flames to decontaminate environmental surfaces for *Salmonella* control.
- Immersion of small components (i.e. knives, small parts, eating utensils and small containers) into water heated to 82°C for a few seconds.
- The use of 'dry' steam generators for the local application of steam, e.g. on conveyor belts.
- The placement of small items of difficult to clean equipment in ovens. A time temperature equivalent of 70°C for 2min is a target thermal

treatment for all equipment surfaces and can be measured using thermocouples.

- The use of steam in enclosed plastic tents for the disinfection of large equipment items, e.g. cooked meat slicing machines. Again, steam is applied for long enough to achieve a 70°C for 2min target thermal treatment.

However, for open surfaces, the use of hot water, steam or naked flames is uneconomic, difficult to maintain target temperatures, may bake on residues, is hazardous to operatives, and reliance is, therefore, placed on chemical biocides. The ideal chemical disinfectant should have the following characteristics:

- Microbial destruction properties of uniform, broad-spectrum activity against viruses, vegetative bacteria, yeasts and moulds to produce rapid kill.
- Environmental resistance (effective in the presence of organic matter, detergent and soap residues, and water hardness and pH variability).
- Good cleaning properties.
- Non-toxic and non-irritating properties.
- Water solubility in all proportions.
- Non-tainting, particularly for 'non-rinse' disinfectants.
- Stability in concentrated and use dilution.
- Ease of use.
- Ready availability.
- Inexpensive.
- Ease of measurement in solution.

Whilst there are many chemicals with biocidal properties, some common disinfectants are not used in food applications because of safety or taint problems, e.g. phenolics or metal-ion-based products. In addition, other disinfectants are used to a limited extent only in chilled food manufacture and/or for specific purposes, e.g. peracetic acid, biguanides, formaldehyde, glutaraldehyde, organic acids, ozone, chlorine dioxide, bromine and iodine compounds. In a (Campden BRI) survey undertaken of the UK food industry in 2000, of 117 food premises incorporating farms, food manufacturers, food hauliers and caterers, 70% used quaternary ammonium compound, (QACs), 49% chlorine-releasing agents, 26% alcohol, 10% amphoterics and 7% peracetic acid. Of the acceptable chemicals, therefore, the most commonly used products for open and closed surface disinfection are:

- chlorine-releasing components;
- QACs;
- amphoteric compounds;
- alcohols;
- peracetic acid.



Chlorine is the cheapest disinfectant and is available as hypochlorite (or occasionally as chlorine gas) or in slow-release forms (e.g. chloramines, dichlorodimethylhydantoin). Hypochlorous acid, the disinfectant active, is produced when all of these chlorine sources are added to water. Hypochlorous acid has a wide range of activity, including against spores, and is relatively inexpensive. However, it is readily inactivated by organic matter, and may be viewed by some as having an adverse effect on the environment. Chlorine compounds in the undiluted form are corrosive to equipment, can be hazardous to health and should always be handled with care and at the correct concentrations.

QACs (or Quats) are amphipolar, cationic detergents, derived from substituted ammonium salts with a chlorine or bromine anion. Although having little effect on spores, they are both relatively environmentally and operative friendly. It should be noted that certain alkaline compounds (anionic wetting agents) can reduce the bactericidal action of QACs. It should also be noted that:

- QACs are stable in concentrated form and have a long shelf-life.
- In concentrated form they are much safer to handle than hypochlorite solutions and they are relatively non-corrosive to metals.
- Owing to their high surface activity, excessive foam can be produced during circulation through the plant and hence QACs are sometimes difficult to rinse away.
- Factors that can impair their bacteriocidal effectiveness are the presence of organic matter, water hardness which can reduce their activity and the type of organism. Gram negative bacteria like coliforms and psychotrophic organisms may be less affected, especially at low concentrations (e.g. at <50ppm of QAC at 10°C), than Gram-positive bacteria (e.g. staphylococci and streptococci).

Amphoterics are based on the amino acid glycine, often incorporating an imidazole group. They share similar activities and benefits with the quaternary ammonium compounds. Amphoterics are known to have good detergent/sterilising properties, but due to their high foaming characteristics, they are not recommended for cleaning in place (CIP). However, they are used for manual cleaning, since they are non-corrosive and non-irritant to skin.

Within the dry foods industry and the RTE chilled food industry (particularly for mid-shift cleaning and disinfection in high-risk areas), alcohol-based products are commonly used. In these industries water is either strictly limited or prohibited, or is restricted during production periods as a control measure to prevent the growth and spread of any food pathogens. Ethyl alcohol (ethanol) and isopropyl alcohol (isopropanol) have bactericidal and virucidal (but not sporicidal) properties (Hugo and Russell, 1999), though they are only active in the absence of organic matter, i.e. the surfaces need to be wiped clean and then alcohol reapplied. Alcohols

are most active in the 60–70% range, rapidly lose effectiveness if diluted out of this range, and can be formulated into wipe and spray-based products. Alcohol products are used on a small, local scale because of their well-recognised health and safety issues.

Peracetic acid, which provides a rapid, broad-spectrum kill, works on the oxidation principle through the reaction with the components of cell membranes. It is particularly effective against spores but is hazardous to use. It is one of a family of acid disinfectants which are considered to be toxicologically safe and biologically active. They include other organic acids, such as acetic, lactic, propionic and formic acid. Acid anionic disinfectants are formulated with anionic surfactants (negatively charged) acids, phosphoric acid and organic acids. They act rapidly and kill a broad spectrum of bacteria. Whilst peracetic acid has traditionally been used in CIP systems, formulated products are now available for open surface disinfection.

The characteristics of the most commonly used are compared in Table 9.3. The properties of QAC/amphoteric mixes will be similar to their parent compounds with suggested enhanced microorganism control. The table essentially confirms that QACs, amphoterics and alcohol are used predominantly for open plant cleaning because they combine sufficient antimicrobial properties yet are ‘friendly’ to operatives and the processing

**Table 9.3** Characteristics of some universal disinfectants

Property	Chlorine	QAC	Amphoteric	Alcohol	Peracetic acid
Microorganism control					
Gram positive	++	++	++	++	++
Gram negative	++	+	++	++	++
Spores	+	–	–	–	++
Yeast	++	++	++	+	++
Developed microbial resistance	–	+	+	–	–
Inactivation by					
organic matter	++	+	+	++	+
water hardness	–	+	–	–	–
Detergency properties	–	++	+	–	–
Surface activity	–	++	++	–	–
Foaming potential	–	++	++	–	–
Problems with taints	+/-	–	–	–	+/-
Stability	+/-	–	–	–	+/-
Corrosion	+	–	–	–	–
Safety other chemicals	+	–	–	+	++
	–	+	–	–	–
Potential environmental impact	++	-/+	-/+	–	–
Cost	–	++	++	+++	+

– no effect (or problem), + effect, ++ large effect.

environment. Chlorine has excellent antimicrobial properties though, due to its corrosiveness, it is used sparingly on open surfaces and is followed by thorough rinsing. Peracetic acid is perhaps the most antimicrobial chemical to microorganisms in suspension, attached to surfaces and in biofilms (Holah *et al.*, 1990a). However, it is more of a hazard to cleaning operatives and, although it is the most common disinfectant used in closed plant systems, it is only used under controlled conditions for open plant.

The efficacy of disinfectants is generally controlled by five factors: interfering substances (primarily organic matter), pH, temperature, concentration and contact time. To some extent, and particularly for the oxidative biocides, the efficiency of all disinfectants is reduced in the presence of organic matter. Organic material may react chemically with the disinfectant such that it loses its biocidal potency, or spatially such that microorganisms are protected from its effect. Other interfering substances, e.g. cleaning chemicals, may react with the disinfectant and destroy its antimicrobial properties, and it is therefore essential to remove all soil and chemical residues prior to disinfection. This is particularly important with cationic QACs such that, if used, all traces of anionic detergents need to be removed prior to disinfection.

Disinfectants should only be used within the pH range as specified by the manufacturer. Perhaps the classic example of this is chlorine, which from pH 3–7.5 is predominantly present as hypochlorous acid (HOCl), which is a very powerful biocide, though the potential for corrosion increases with acidity. Above pH 7.5, however, the majority of the chlorine is present as the dissociated  $\text{OCl}^-$  ion which has about 100 times less biocidal action than HOCl.

In general, the higher the application temperature the greater the degree of disinfection achieved. For most food manufacturing sites operating at ambient conditions (around 20°C) or higher this is not a problem as most disinfectants are formulated (and tested) to ensure performance at this temperature. This is not, however, the case in the chilled RTE food industry. Taylor *et al.* (1999) examined the efficacy of 18 disinfectants at both 10°C and 20°C and demonstrated that for some chemicals, particularly quaternary ammonium-based products, disinfection was much reduced at 10°C and recommended that in chilled production environments, only products specifically formulated for low-temperature activity should be used.

In practice, the relationship between microbial death and disinfectant concentration is not linear but follows a sigmoidal curve. Microbial populations are initially difficult to kill at low concentrations, but as the biocide concentration is increased, a point is reached where the majority of the population is reduced. Beyond this point the microorganisms become more difficult to kill (through resistance or physical protection) and a proportion may survive regardless of the increase in concentration. It is important, therefore, to use the disinfectant at the concentration recommended by the manufacturer. Concentrations above this recommended

level may thus not enhance biocidal effect and will be uneconomic, whilst concentrations below this level may significantly reduce biocidal action.

Low concentrations of disinfectants may lead to the formation of resistant surface populations. There is evidence that *Pseudomonas aeruginosa* can become adapted by repeated exposure to QACs and amphotericins (Adair *et al.*, 1969; Jones *et al.*, 1989; Langsrud and Sundheim, 1997). Plasmid-mediated resistance has also been described for Gram positive *Staphylococcus* spp. involving the *qacA-D* genes (McDonnell and Russell, 1999) and *qacG-H* genes (Heir *et al.*, 1999). The presence of QAC-resistant staphylococcal strains has been shown to be common in food processing environments by Heir *et al.* (1999) who identified 25 from 191 isolates to be resistant to benzalkonium chloride. In laboratory disinfectant challenge tests, these authors demonstrated an increase in minimum inhibitory concentration (MIC) from 0–2 mg/l to 4–11 mg/l. Similarly, Mereghetti *et al.* (2000) demonstrated an MIC increase in resistance from 3 to 13 mg/l for strains of *L. monocytogenes* isolated from a range of environmental, food, animal and clinical sources. None of these workers demonstrated *Staphylococcus* spp. or *L. monocytogenes* strain resistance to disinfection concentrations approaching disinfectant manufacturers' in-use recommended concentrations. In the UK, good quality QACs have a concentration of approximately 1000 mg/l, indicating no problems with resistant vegetative bacteria if appropriate disinfectants are chosen and used properly.

Sufficient contact time between the disinfectant and the microorganisms is perhaps the most important factor controlling biocidal efficiency. To be effective, disinfectants must find and concentrate at, bind to and transverse microbial cell envelopes before they reach their target site and begin to undertake the reactions which will subsequently lead to the destruction of the microorganism (Klemperer, 1982). Sufficient contact time is therefore critical to give good results, and most general-purpose disinfectants are formulated to require at least 5 minutes to reduce bacterial populations by 5 log orders in suspension. This has arisen for two reasons. Firstly 5 minutes is a reasonable approximation of the time taken for disinfectants to drain off vertical or near vertical food processing surfaces. Secondly, when undertaking disinfectant efficacy tests in the laboratory, a 5-minute contact time is chosen to allow ease of test manipulation and hence timing accuracy. For particularly resistant organisms such as spores or moulds, surfaces should be repeatedly dosed with disinfectant to ensure extended contact times of 15–60 minutes.

## 9.5 Testing disinfectants

Ideally, disinfectants should have the widest possible spectrum of activity against microorganisms, including bacteria, fungi, spores and viruses, and

this should be demonstrable by means of standard disinfectant efficacy tests. The range of currently available disinfectant test methods was reviewed by Reybrouck (1998). They fall into two main classes, suspension tests and surface tests. Suspension tests are useful for indicating general disinfectant efficacy and for assessing environmental parameters such as temperature, contact time and interfering matter such as food residues. In reality, however, microorganisms disinfected on food contact surfaces are those that remain after cleaning and are therefore likely to be adhered to the surface. A surface test is thus more appropriate.

A number of authors have shown that bacteria attached to various surfaces are generally more resistant to biocides than are organisms in suspension (Ridgeway and Olsen, 1982; Hugo *et al.*, 1985; LeChevalier *et al.*, 1988; Frank and Koffi, 1990; Holah *et al.*, 1990a; Lee and Frank, 1991; Wright *et al.*, 1991; Dhaliwal *et al.*, 1992; Das *et al.*, 1998; Andrade *et al.*, 1998). In addition, cells growing as a biofilm have been shown to be more resistant (Frank and Koffi, 1990; Lee and Frank, 1991; Ronner and Wong, 1993). The mechanism of resistance in attached and biofilm cells is unclear but may be due to physiological differences such as growth rate, membrane orientation changes due to attachment and the formation of extracellular material which surrounds the cell, or genetic. Equally, physical properties may have an effect, e.g. protection of the cells by food debris or the material surface structure or problems in biocide diffusion to the cell/material surface. To counteract such claims of enhanced surface-adhered resistance, it can be argued that, in reality, surface tests do not consider the environmental stresses the organisms may encounter in the processing environment prior to disinfection (action of detergents, variations in temperature and pH and mechanical stresses) which may affect susceptibility (Walton *et al.*, 2008). Both suspension and surface tests, therefore, have their limitations (Holah *et al.*, 1998).

The current European food industry disinfectant test methods of choice for bactericidal and fungicidal action in suspension are EN 1276 (Anon., 1997) and EN 1650 (Anon., 1998a) respectively and food manufacturers should ensure that the disinfectants they use conform to these standards as appropriate. In particular, for low temperature food processing areas, evidence of performance against EN 1276 at 10°C should be sought from disinfectant manufacturers.

The surface test, EN 13697 (Anon., 2001), is also available for disinfectant manufacturers to demonstrate efficacy of their products against surface-adhered microorganisms. Because of the limitations of disinfectant efficacy tests, however, food manufacturers should always confirm the efficacy of their cleaning and disinfection programmes by 'field tests', either from evidence supplied by the chemical company or from in-house validation trials.

As well as having demonstrable biocidal properties, disinfectants must also be safe (non-toxic) and should not taint food products. Disinfectants

can enter food products accidentally, e.g. from aerial transfer or poor rinsing, or deliberately, e.g. from 'no rinse status' disinfectants. The practice of rinsing or not rinsing has been under discussion for many years and has yet to be clarified. The main reason for leaving disinfectants on surfaces is to provide an alleged biocide challenge to any subsequent microbial contamination of the surface or when the quality of the final rinse water is not known. It has been argued, however, that the low biocide concentrations remaining on the surface, especially if the biocide is a QAC, may lead to the alleged formation of resistant surface populations. In Europe there is no legislation requiring disinfectants to be rinsed from surfaces other than the general Directive on the hygiene of foodstuffs (93/43/EEC) which requires 'Food business operators shall identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed ...'. In other words disinfectants can be left on surfaces if the food manufacturer is happy that any residues will not affect the wholesomeness or safety of subsequently produced foodstuffs.

In terms of the demonstration of non-toxicity, legislation will vary in each country although in Europe, this will be clarified with the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market, which contains requirements for toxicological and metabolic studies. This Directive seeks to produce a list of active biocidal substances that have been assessed for both their toxicological properties and also their inherent antimicrobial properties. Following the establishment of the approved active list, formulated products (the disinfectants sold to the final user) can then only be made by incorporating an approved active ingredient and the formulated product will then itself be assessed for its toxicological and antimicrobial properties. The effects of this Directive are already being seen, as current formulated products that do not contain biocidal active ingredients that will be supported through the approval process are being removed from the marketplace. This will undoubtedly reduce the choice of disinfectants available to the food industry in the future, though the ones that will be available will have been thoroughly assessed. In the interim, a recognised acceptable industry guideline for disinfectants is a minimum acute oral toxicity (with rats) of 2000 mg/kg bodyweight.

Historically, approximately 30% of food taint complaints are thought to be associated with cleaning and disinfectant chemicals and are described by sensory scientists as 'soapy', 'antiseptic' or 'disinfectant' (Holah, 1995). Campden BRI has developed two taint tests in which foodstuffs which have and have not been exposed to disinfectant residues are compared by a trained taste panel using the standard triangular taste test (Anon., 1983a). For assessment of aerial transfer, a modification of a packaging materials odour transfer test is used (Anon., 1964) in which food products, usually of four types (high moisture, e.g. melon, low moisture, e.g. biscuit, high fat, e.g.

cream, high protein, e.g. chicken) are held above a disinfectant solution or distilled water for 24 hours. To assess surface transfer, a modification of a food container transfer test is used (Anon., 1983b) in which food products are sandwiched between two sheets of stainless steel and left for 24 hours. Disinfectants can be sprayed onto the stainless steel sheets and drained off, to simulate no rinse status, or can be rinsed off prior to food contact. Control sheets are rinsed in distilled water only. The results of the triangular test involve both a statistical assessment of any flavour differences between the control and disinfectant treated sample and a description of any flavour changes.

## 9.6 Water quality

With respect to water use in food manufacturing in the EU, Regulation (EC) 852/2004 (Anon., 2004) states that there is to be an adequate supply of potable water, which is to be used whenever necessary to ensure that food stuffs are not contaminated, Annex II, Chapter VII, 1(a). This implies that only potable water can be used as a product ingredient, processing aid and for food contact surface cleaning and disinfection, a view endorsed by Dawson (1998) and the Chilled Food Association *Water quality management guidance*, 2005 ([www.chilledfood.org](http://www.chilledfood.org)). However, it goes on to say that recycled water used in processing or as an ingredient is not to present a risk of contamination. It is to be of the same standard as potable water, unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the product in its finished form. This is a new insertion as compared to the last EU General Hygiene Directive (EC/93/43), in which only the use of potable water was inferred. This now suggests that food manufacturers could promote sustainable water use and make considerable cost savings on both reduced water supply and effluent discharge if they could safely reuse water for other potable purposes, e.g. cleaning. The risks and control of the reuse of potable water are discussed in Holah (2012).

In addition, the degree of hardness must be taken into account in assessing water quality. This latter aspect is important, since detergents are formulated in relation to the degree of water hardness, and the presence of excess inorganic salts, mainly calcium and magnesium, can reduce their effectiveness. In addition, these salts can leave deposits on the surfaces of equipment which are difficult to remove. Water hardness is measured according to the mass of dissolved calcium and magnesium salts in the water. Other general measures of water quality include pH, conductivity or chlorine concentration (Anon., 1993). Whilst the main responsibility for meeting these standards lies with those supplying water to the food industry, food processors need to be aware of them, partly to ensure they are included in contractual agreements with water suppliers, and partly because many



food processors undertake additional disinfection processes which may alter water composition and quality (Dawson, 1998).

The water used in a food processing plant for cleaning and other purposes must be properly stored and managed. Storage systems should be designed with no dead ends so that water may circulate or flow freely (Imholte, 1984). Water should not be allowed to stagnate. In an old plant with extensive pipe runs, 'dead ends' or 'dead sections' can present real problems and have been known to be the explanation of sudden and unacceptably high numbers of microorganisms and taints. Water supplies should therefore be installed or modified to eliminate dead ends. Water lines no longer in use should be removed. Contamination from rust, scale and grease can also occur and pipes and pumps must be regularly inspected and properly maintained. New water piping installations should be made of corrosion-resistant materials.

All potable water storage tanks should be fitted with closely fitting covers to exclude contamination from dust, insects, birds or rodents. They should also be fitted with a means of access to permit cleaning not less than once a year. Water in tanks should be sampled for microbiological and other contamination at regular intervals. In general, storage tanks and pipes should meet the same hygienic design criteria as other equipment in such areas as drainability and cleanability (see Chapter 4). It is important to keep accurate records of the water supply system to anticipate or resolve any contamination problems.

Temperature control is also important: to maintain cold water lines below the recommended 20 °C (68 °F) insulation may be needed. In a large plant, the 'potable water' system may include heat-regenerating units and heat exchangers to provide a piped hot water system, as well as high-pressure hot and/or cold hose lines for cleaning purposes. It is good practice to keep the length of 'spurs' or 'branches' to less than 6 m, and to lag hot water lines. This will mean that they can deliver water consistently at the required temperature and/or pressure.

Both cross-connections and backflows can cause unexpected problems in a processing plant. A cross-connection is a physical connection, either temporary or permanent, between systems such that the water can flow between them. A backflow or back-siphonage occurs when contaminated water is drawn back by reduced pressure into a potable water line. Backflow preventers or vacuum-breakers should be used where required.

It is very important that non-potable water supplies should always be recognised as a source of potential danger. Potable and non-potable water should be in separate, independent distribution systems. It is not acceptable to rely on separation or isolation by valve arrangements. Valves can and do leak and pressure differentials may be momentarily altered or reversed. Potable water used to supplement any non-potable supply must always be positively protected against contamination from back-pressure or siphonage, e.g. by an adequate airgap. Non-potable lines must be clearly and readily identified as such.

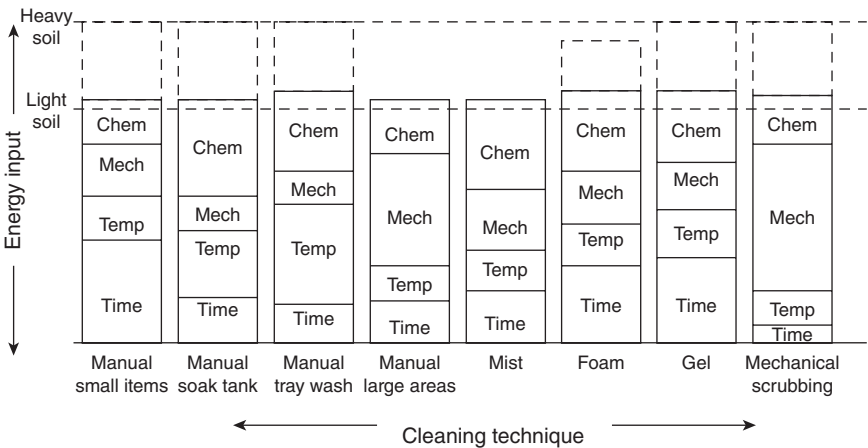


### 9.7 Sanitation methodology

Cleaning and disinfection can be undertaken by hand using simple tools, e.g. brushes or cloths (manual cleaning), though as the area of open surface requiring cleaning and disinfection increases, specialist equipment becomes necessary to dispense chemicals and/or provide mechanical energy. Chemicals may be applied as low-pressure mists, foams or gels, whilst mechanical energy is provided by high- and low-pressure water jets or water or electrically powered scrubbing brushes. These techniques have been well documented (Marriott, 1985; Anon., 1991; Holah, 1991) and as with cleaning chemicals, have changed little since these reviews: this section considers their use in practice.

The use of cleaning techniques can perhaps be described schematically following the information detailed in Fig. 9.2 (modified from Offiler, 1990). The figure details the different energy source inputs for a number of cleaning techniques and shows their ability to cope with both low and high (dashed line) levels of soiling. For the manual cleaning of small items a high degree of mechanical energy can be applied directly where it is needed and with the use of soak tanks (or clean-out-of-place techniques) contact times can be extended and/or chemical and temperature inputs increased such that all soil types can be tackled.

Alternatively, dismantled equipment and production utensils may undergo manual gross soil removal and then be cleaned and disinfected automatically in tray or tunnel washers. As with soak tank operations, high levels of chemical and thermal energy can be used to cope with the majority of soils. Industrial tray washes should be sited in separated areas with good air extraction and make-up facilities which can be closed off from production



**Fig. 9.2** Relative energy source inputs for a range of cleaning techniques (modified from Offiler, 1990).

areas, as they are prone to microbial aerosol production which may lead to aerial product contamination (see Chapter 7).

In manual cleaning of larger areas, especially above chest level, for reasons of operator safety, cleaning operatives should only use low-temperature water ( $<60^{\circ}\text{C}$ ) and low levels of chemical energy. As the surface area requiring cleaning increases, manual techniques become uneconomic with respect to time and labour. Labour costs amount to 75% of the total sanitation programme and for most food companies, the cost of extra staff is prohibitive. Only light levels of soiling can be economically cleaned by this method.

The main difference between the mist, foam and gel techniques is in their ability to maintain a detergent/soil/surface contact time. For all three techniques, mechanical energy can be varied by the use of high- or low-pressure water rinses, though for open surface cleaning, temperature effects are minimal. Mist spraying is undertaken using small hand-pumped containers, 'knapsack' sprayers or pressure washing systems at low pressure. Misting will only 'wet' vertical smooth surfaces; therefore only small quantities can be applied and these will quickly run off to give a contact time of 5 minutes or less. Because of the nature of the technique to form aerosols that could be an inhalation hazard, only weak chemicals can be applied, and so misting is useful only for light soiling. On cleaned surfaces, however, misting is the most commonly used method for applying disinfectants.

Foams can be generated and applied by high-pressure equipment with entrapment of air in the foam or by the addition of compressed air in low-pressure systems. Foams work on the basis of reducing the density of the cleaning agent and forming a layer of bubbles above the surface to be cleaned which then collapses and bathes the surface with fresh detergent contained in the bubble film. The critical element in foam generation is for the bubbles to collapse at the correct rate: too fast and the contact time will be minimal; too slow and the surface will not be wetted with fresh detergent.

Gels are thixotropic chemicals which are fluid at high and low concentrations but become thick and gelatinous at concentrations of approximately 5–10%. Gels are easily applied through high- and low-pressure systems or from specific portable electric pumped units and physically adhere to the surface. Gels may be coloured to show coverage.

Foams and gels are more viscous than mists, are not as prone to aerosol formation and thus allow the use of more concentrated detergents, and can remain on vertical surfaces for much longer periods (foams 10–15 minutes, gels 15 minutes to an hour or more). Foams and gels are able to cope with higher levels of soils than misting, therefore, although in some cases rinsing of surfaces may require large volumes of water, especially with foams. Foams and gels are well liked by operatives and management as, because of the nature of the foam, a more consistent application of chemicals is possible and it is easier to identify areas that have been 'missed'.

Cleaning chemicals are removed from surfaces by low-pressure/high-volume (LPHV) hoses operating at mains water pressure (typically <10 bar) or by high-pressure/low-volume (HPLV) pressure washing systems which require a high-pressure pump. High-pressure washing systems operate above mains water pressure, typically at between 25–100 bar through a 15° nozzle, and may be mobile units, wall-mounted units or centralised ring-mains. Water jets confer high mechanical energy, can be used on a wide range of equipment and environmental surfaces, will penetrate into surface irregularities and are able to mix and apply chemicals.

Mechanical scrubbers include traditional floor scrubbers, scrubber/driers (automats) for floors, water-driven attachments to high-pressure systems and electrically operated small-diameter brushes that can be used on floors, walls and other surfaces. Contact time is usually limited with these techniques (though can be increased), but the combination of detergency with high mechanical input allows them to tackle most soil types. These techniques work best when the food processing areas to be cleaned have been designed or refurbished to suit their use (primarily to facilitate ease of access).

The hygienic implications of the design and use of all cleaning equipment should be carefully considered and should be similar to that required for other food processing equipment (Chapter 4). Sanitation equipment should be constructed out of smooth, non-porous, easily cleanable materials such as stainless steel or plastic. Mild steel or other materials subject to corrosion may be used but must be suitably painted or coated, whilst the use of wood is unacceptable. Frameworks should be constructed of tubular or box section material, closed at either end and properly jointed, e.g. welds should be ground and polished and there should be no metal-to-metal joints. Crevices and ledges where soil could collect should be prevented and exposed threads should be covered or dome nuts used. Tanks for holding cleaning chemicals or recovered liquids should be self-draining, have rounded corners and should be easily cleaned. Shrouds around brush heads or hoods and rotary scrubbing heads should be easily detachable to facilitate cleaning. Brushes should have bristles of coloured, impervious material, e.g. nylon, embedded into the head with resin so no soil trap points are apparent. Alternatively, brushes with the head and bristles moulded as one unit may be used.

Cleaning equipment is prone to contamination with *Listeria* spp. and other pathogenic microorganisms and, by the nature of its use, provides an excellent way in which contamination can be transferred from area to area. Cleaning equipment should be segregated for different areas of the food processing environment and can be differentiated by colour coding, e.g. drains (black), environmental surfaces (yellow) and food contact surfaces (white). Cleaning equipment should also be specific to high hygiene areas and, after use, equipment should be thoroughly cleaned and, if appropriate, disinfected and dried.

The potential for cleaning equipment to disperse microbial contamination by the formation of aerosols has been reported (Holah *et al.*, 1990b) and it was shown that all cleaning systems tested produced viable bacterial aerosols from test surfaces contaminated with attached biofilms. The degree of contamination impinging on a surface was graded from total coverage to the minimum level thought likely to give food safety concerns if a proportion of the droplets contained viable microorganisms, and the maximum height and distance travelled by these potentially contaminating droplets are shown in Table 9.4. Assuming an average food contact surface height of 1 m, the results suggest that both the HPLV and LPHV techniques disperse a significant numbers of droplets to this height and should not, therefore, be used during production periods. The other techniques, however, are acceptable for use in clean-as-you-go operations as the chance of contamination to product is low, though care is needed when using floor scrubber/driers (these are useful in that the cleaning fluid is removed from the floor) if product is stored in racks close to the floor. After production, HPLV and LPHV techniques may be safely used (and are likely to be the appropriate choice), but it is required that disinfection of food contact surfaces is the last operation to be performed within the sanitation programme. Subsequent work has shown that reducing water pressure or changing impact angle made little difference to the degree of aerosol spread for HPLV and LPHV systems, dispersal to heights >1 m still being achieved.

Dry cleaning methods are used where the food soils are hygroscopic or where water can react to form hard deposits which are difficult to remove.

**Table 9.4** Maximum height and distance spread of aerosol (droplet) impingement for a number of wet cleaning techniques and dry powder dispersion for dry cleaning techniques

Cleaning technique	Wet droplet dispersion		Dry powder dispersion	
	Height (cm)	Distance (cm)	Distance (cm)	Width (cm)
High-pressure/ low-volume spray lance	309	700		
Low-pressure/ high-volume hose	210	350		
Floor scrubber/ drier	47	80		
Manual brushing	24	75	85–100*	0
Manual wiping	23	45		
Vacuum			30	0
Compressed air			>150	115

\*85–110cm for soft and medium bristles respectively.

The principal risk is that failure to control moisture can permit the growth of pathogens, e.g. *Salmonella* spp., in the processing environment which then contaminates any food being processed. Environments usually dry cleaned include plants producing flour, chocolate, peanut butter, dry milk products, dry soup and snack mixes, and dry infant formulae. Dry cleaning is essentially the mechanical removal of soils using sweeping, brushing, wiping, vacuuming and compressed air or the use of alcohol-impregnated wipes.

As for wet cleaning techniques, however, dry cleaning techniques can create dry aerosols, some of which may contain microorganisms or allergens. Work at Campden BRI assessed the degree of aerosol spread of a range of dry cleaning techniques when cleaning dry powders (flour and rice soils) and two-dimensional spread results are shown in Table 9.4. When using a vacuum head with bristles, there was some movement of the dry powder in a forward direction, though this was minimal and in reality, the vast majority of the dry powder was picked-up by the vacuum. Both brushing and the use of compressed air moved dry powders significant distances, with compressed air giving a much wider distribution pattern. In three-dimensional studies, however, the height and length of time that particles were airborne was low for brushing whilst powders aerosolised by compressed air, particularly in the range of 10–25 µm, remained airborne for >16 min. This is important as it is known that particles of this size can carry microorganisms and, when subjected to natural factory air movements, these particles can be carried substantial distances, potentially to areas where they could be a risk to product quality or safety. Compressed air cleaning should also not be used during production in high hygiene areas. Particle counting studies also showed that vacuum cleaners with good quality microbiological filters (not necessarily high-efficiency particulate air, HEPA) produced few particles from their exhausts and that in any case, particles from the exhausts were small in comparison with particles generated from the external surfaces of the vacuum cleaners when the cleaners were switched on. Vacuum cleaners should not be moved around different hygiene risk zones in factories but should be dedicated to specific areas.

## 9.8 Wholeroom disinfection

The primary focus of sanitation procedures is food production equipment and much of the rest of the processing area, whilst cleaned, is not routinely disinfected. This targeted approach has been sufficient to maintain day-to-day control of contamination of foodstuffs, but cannot eliminate all of the microorganisms in the processing environment and may have contributed to the development of persistent stains. Disinfection systems for the air and all environmental surfaces in the processing area, 'wholeroom disinfection', may have benefits in controlling such microorganisms.

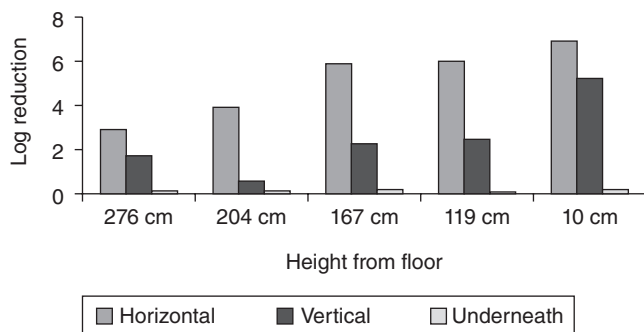
A number of techniques are now available that have the ability to disinfect large areas. These include traditional chemical fogging, the use of UV light, commercially available ozone and hydrogen peroxide systems. Chlorine dioxide systems are the method of choice for many western governments for the disinfection of biological 'incidences', but chlorine dioxide systems are not yet readily available commercially. All of these systems require the process area to be isolated, all staff to be removed, and for the area to be made safe before reoccupation by staff.

Applying chemical disinfectants to production areas as fogs or mists is a method that has been used routinely in the food industry to control cross-contamination. The purpose of fogging is to create and disperse a disinfectant aerosol, usually QACs or peracetic acid, to supersaturate the atmosphere and thus reduce the numbers of airborne microorganisms and also to apply disinfectant to surfaces that may be difficult to reach, such as overhead surfaces. Fogging is done by using either a static, purpose-built system in an area of a factory with strategically placed nozzles, or more commonly by using a mobile unit.

Research carried out by Burfoot *et al.* (1999) demonstrated that fogging was most effective when using compressed air-driven fogging nozzles producing fog droplets with a median diameter of between 10 and 20  $\mu\text{m}$ , as the droplets in this size range dispersed well and settled within 45 minutes. An air velocity of 100  $\text{ms}^{-1}$  was required at the nozzle for effective dispersal of the chemical. Larger particles can be used if the air velocity is increased or fans are used to assist with the distribution of the droplets. Under typical conditions, fogging is carried out for a minimum of 15 to 30 minutes to enable the fog to disperse and the chemical action to occur, and after fogging a period of 45 to 60 minutes is required to allow the droplets to settle out of the air and onto the surfaces, reducing the risk of operators inhaling the chemical droplets (Anon., 1998b).

For surface disinfection, fogging is only effective if sufficient chemical can be deposited onto the surface. This is illustrated in Fig. 9.3 which shows the log reductions achieved on horizontal, vertical and upturned (underneath) surfaces arranged at five different heights from just below the ceiling (276 cm) to just above the floor (10 cm) within a test room. It can be seen that disinfection is very good ( $>5$  log orders) on horizontal surfaces closest to the floor and that disinfection is minimal ( $<1$  log order) on upturned surfaces close to the ceiling. Commercial fogging units are now available which electrostatically charge the disinfectant during the fogging process.

Commercial ultraviolet light units, typically of low-pressure mercury vapour lamps, can be installed on the walls of food production areas. Ultraviolet light as an antimicrobial agent has been used for many years and is effective against a wide range of microorganisms. Decimal reduction values for many strains of microorganism have been established



**Fig. 9.3** Comparative log reductions of microorganisms adhered to surfaces and positioned at various heights and orientations.

experimentally and are expressed as a dose, which is a combination of intensity and time. Units can be sized, therefore, to ensure that a sufficient dose, e.g. to provide a 3 or 4 log reduction of target strains of microorganism, is achieved throughout the processing area. To be effective, however, the light rays must actually impact on the microorganisms, and microorganisms in any shadow areas, where the light does not reach, will be protected. Equally, dust, thin soil films and opaque or turbid solutions can absorb the ultraviolet light. As yet, ultraviolet light is not widely used for wholeroom disinfection.

Due to its rapid degradation into innocuous by-products, decontamination with hydrogen peroxide vapour (HPV) is a technique that has been widely used for disinfection of the pharmaceutical environment, including clean rooms and production filling lines and is beginning to be used in the food industry. The application of HPV is said to have excellent material compatibility and is safe for use on a wide range of metals, including stainless steel and aluminium, plastics such as polypropylene and polycarbonate, and other materials, such as electronic circuitry.

Mobile systems can be used throughout the factory environment, or areas can be equipped with ports to which the equipment can be docked while the decontamination procedure is carried out. A number of commercial systems are available which have slight operational differences, but the most commonly used aqueous solution of  $\text{H}_2\text{O}_2$  is 30 or 35% w/w, which is frequently evaporated to produce  $\text{H}_2\text{O}_2$  concentrations ranging from 0.1 to  $10\text{ mg L}^{-1}$  (0.0001 to 0.001%) depending on the exposure temperature, which ranges from 4 to  $80^\circ\text{C}$ . HPV is applied to the room in a heated carrier gas, initially air, and vapours from the room are returned to the gas generator where further quantities of the  $\text{H}_2\text{O}_2$  are evaporated. As more vapour is introduced into a room, the pressure and concentration of the peroxide/water vapour will increase. The gaseous state is therefore advantageous because it ensures uniform contact with all surfaces, including horizontal and vertical surfaces and cracks. The term 'dry fog' is sometimes used to



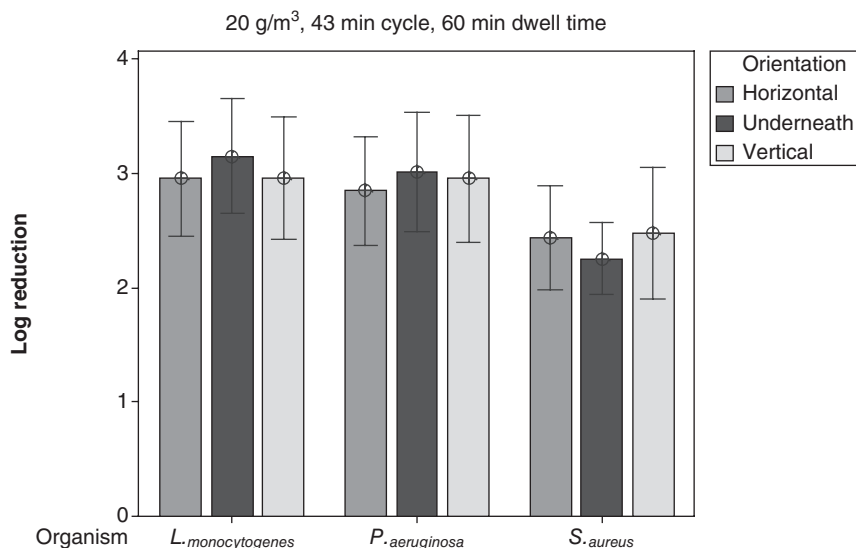
describe the vapour with droplet sizes below 10 µm. Hydrogen peroxide gas diffuses passively when introduced into a given area and therefore constant movement of the gas is required to ensure that all surfaces are contacted. This can be aided at atmospheric pressure by using fans or air-handling systems, or by introducing a slight positive or negative pressure in the area being fumigated.

Hydrogen peroxide demonstrates a broad spectrum of efficacy against viruses, bacteria, mycobacteria, fungi and bacterial spores. HPV damages cellular proteins, lipids and nucleic acids, and the increased reactivity of the gaseous peroxide may be due to the greater presence of the short-lived radicals and ions that form. It is more effective against Gram positive than Gram negative bacteria; however, the presence of catalase or other peroxidases, particularly in Gram positive bacteria, such as *Staphylococcus* spp., allows increased tolerance, due to enzymatic degradation.

Ozone (O<sub>3</sub>), which has been used for many decades for water treatment, is an activated form of oxygen, which is unstable and breaks down into three atoms of oxygen. High reactivity, penetrability and spontaneous decomposition into a non-toxic product make ozone a viable disinfectant for use in food production areas. Due to its reactive, unstable nature, ozone is produced at the point of use. Ozone generators effectively pass air through a high-energy source within the equipment and the resulting physicochemical reaction leads to the formation of ozone that can be used for area or surface decontamination. Widely used high-energy sources include UV light, electrochemical cells or corona discharge. A corona is formed by an electrical discharge around a gas, which causes ionisation and consequently the formation of ozone. The production of ozone is most effective in a temperature-controlled environment, since the stability of ozone decreases as the temperature increases.

Microorganisms inherently vary in their sensitivity to ozone with factors such as temperature, humidity, presence of chemicals and the amount of organic matter surrounding the cell also greatly affecting the degree of inactivation. At the concentrations typically used, ozone is an effective against bacteria and viruses, though less effective against spores. Work by Fan *et al.* (2007) showed that the average time for a 2 log reduction of *Listeria innocua* on solid media was 1.3 hours at 20 °C, and 2.5 hours at 5 °C at 100 nl L<sup>-1</sup> ozone concentration. A study in 2000 at Campden BRI indicated a 2 log reduction in both airborne and surface-adhered *Ps. aeruginosa* in 2 h when exposed to 2 ppm ozone. A more recent study (Malinowska and Holah, 2010) assessed the effectiveness of HPV and ozone under laboratory and industrial conditions. Both of these applications differ from chemical fogging in that they are effective on horizontal, vertical and underneath surfaces (Fig. 9.4) and, as such, are able to penetrate into many geometric shapes to provide effective disinfection. The results in Fig. 9.4 are for HPV, but ozone behaved in exactly the same way, and showed no statistical difference between orientations for the three microorganisms tested.





**Fig. 9.4** Comparative log reductions of microorganisms adhered to surfaces and positioned at various heights and orientations for HPV for *L. monocytogenes*, *Pseudomonas aeruginosa* and *Staphylococcus aureus*.

At concentrations of 20 g/m<sup>3</sup>, HPV produced an approximately 3 log reduction for *Ps. aeruginosa*, *Staphylococcus aureus* and *L. monocytogenes* in 2–4 hours. At this concentration of HPV, the vegetative microorganisms (all of which are catalase positive) were all able to partially resist the concentration/volume of disinfectant that they came into contact with. When the HPV concentration was increased to 40 g/m<sup>3</sup>, an increase in susceptibility was seen for *P. aeruginosa* and *L. monocytogenes*, resulting in a log reduction in excess of 4 logs for *P. aeruginosa* and 5 logs for *L. monocytogenes* at 40 g/m<sup>3</sup>, though there was no increase in the log reduction for *S. aureus*.

A relationship between ozone concentration and log reduction was established, log reductions of approximately 4 log orders were achieved for *L. monocytogenes* and *P. aeruginosa* in 4 hours. It may be possible to express ozone as a dose in terms of concentration hours and from experimental data, a dosage of at least 90 ppm/hour may be required to produce a 5–6 log reduction in vegetative microorganisms (e.g. *L. monocytogenes*). This could be undertaken at 90 ppm for one hour or, for example, 30 ppm for 3 hours.

It is believed that both HPV and ozone in the air behave like chlorine in water, in that there is a HPV or ozone ‘demand’ of oxidisable material to be satisfied in the processing area before ‘free’ HPV or ozone is available to react with microorganisms. It may take a number of hours or even days, therefore, for these chemicals to be effective in food processing

environments. A small number of factories in the UK are beginning to use ozone as a replacement for chemical disinfection. In this case, sanitation involves a rinse, a detergent clean, a rinse and then a gaseous ozone treatment. In a 4 week field trial at one factory utilising a daily ozone treatment of 8ppm for 30 minutes, there was no evidence that ozone was unable to maintain control of the microflora of the food contact surfaces after disinfection. Total viable counts (TVC) after disinfection for ozone-treated food contact surfaces compared favourably to the post-chemical disinfection counts conducted at other, similar chilled food plants. No adverse effects were reported for ozone on the structure and fabric of the building since the ozonation equipment has been installed.

Wholeroom techniques are thus at an early stage in the food industry and the practical considerations related to their use in the food processing environment including concentrations and contact times, health and safety issues and any effect on the fabric of the equipment and the environmental building materials have still to be elucidated. There is also a need to understand how often a whole room disinfection method should be used in the production area; on a daily basis, after the routine cleaning and disinfection procedure has been implemented, or as a replacement for the terminal disinfection step. There is also the option to use a whole room disinfection technique as part of the periodic cleaning and disinfection procedures which may occur monthly, quarterly or annually, or they may only be used for decontaminating an area after a pathogen contamination incident.

An alternative approach to wholeroom disinfection would be to use as many antimicrobial surfaces as possible within food processing equipment and in the environment. The clinical sector has had more experience of these materials than the food industry, particularly surfaces incorporating copper (O’Gorman and Humphries, 2012) and silver (Edwards-Jones, 2009), though, as yet, their antimicrobial role has not been fully established. This is primarily concerned with the need for water to be present on the surface to facilitate the diffusion of the biocide in the antimicrobial material to surface-attached microorganisms, a condition which many food manufacturers are trying to prevent by maintaining their food processing environments as dry as possible.

## 9.9 Sanitation procedures

Sanitation procedures are concerned with both the stage at which the sanitation programme is implemented and the sequence in which equipment and environmental surfaces are cleaned and disinfected within the processing area. Sanitation programmes are so constructed as to be efficient with water and chemicals, to allow selected chemicals to be used under their optimum conditions, to be safe in operation, to be easily managed and to

reduce manual labour. In this way effective sanitation will be achieved, economically and with due regard to environmental discharges and energy and chemical use. The principal stages involved in a typical sanitation programme are given below.

### **9.9.1 Production**

In-production cleaning is best undertaken using dry methods or those using minimum water so as to prevent the growth and spread of pathogenic microorganisms during production periods. Production staff should be encouraged to operate good housekeeping practices (this is an aid to ensuring acceptable product quality and personnel safety), to clean their work stations prior to break periods (unless cleaning operatives are employed specifically to do this) and to leave their work stations in a hygienic condition. Food debris left in hoppers and on process lines, etc., is wasted product! Sound sanitation practices should be used to clean up major product spillages and re-start production which may require the use of wet cleaning methods.

### **9.9.2 Preparation**

As soon as possible after production, equipment for manual cleaning should be dismantled as far as is practicable or necessary to make all surfaces that soiling could have adhered to during production accessible to the cleaning fluids. All product and unwanted utensils/packaging/equipment should be covered or removed from the area. Dismantled equipment should be stored on racks or tables, not on the floor! Machinery should be switched off, at the machine and at the power source, and electrical and other sensitive systems protected from water/chemical ingress. Preferably, production should not be done in the area being cleaned, but in exceptional circumstances if this is not possible, other lines or areas should be screened off to prevent transfer of debris as aerosols or splashes by the sanitation process.

### **9.9.3 Gross soil removal**

Where appropriate, all loosely adhered or gross soil should be removed by brushing, scraping, shovelling or vacuum, etc. Wherever possible, soil on floors and walls should be picked up and placed in suitable waste containers rather than washed into drains using hoses.

### **9.9.4 Pre-rinse**

Surfaces should be rinsed with low-pressure cold water to remove loosely adhered small debris. Hot water can be used for fatty soils (approximately 60°C), but too high a temperature (>45°C) may coagulate proteins.

### **9.9.5 Cleaning**

A selection of cleaning chemicals, temperature and mechanical energy is applied to remove adhered soils.

### **9.9.6 Inter-rinse**

Both soil detached by cleaning operations and cleaning chemical residues should be removed from surfaces by rinsing with low-pressure cold water.

### **9.9.7 Disinfection**

Chemical disinfectants (or occasionally heat) are applied to remove and/or reduce the viability of remaining microorganisms to a level deemed to be of no significant risk. In exceptional circumstances and only when light soiling is to be removed, it may be appropriate to combine stages 5–7 by using a chemical with both cleaning and antimicrobial properties (detergent-sanitiser).

### **9.9.8 Post-rinse**

Disinfectant residues should be removed by rinsing away with low-pressure cold water of known potable quality. Some disinfectants, however, are intended to be left on surfaces until the start of subsequent production periods and are thus so formulated to be both surface-active and of low risk, in terms of taint or toxicity, to foodstuffs.

### **9.9.9 Inter-production cycle conditions**

A number of procedures may be undertaken, including the removal of excess water and/or equipment drying, to prevent the growth of microorganisms on production contact surfaces in the period up until the next production process. Alternatively, the processing area may be evacuated and fogged with a suitable disinfectant.

### **9.9.10 Periodic practices**

Periodic practices increase the degree of cleaning for specific equipment or areas to return them to acceptable cleanliness levels. They include weekly acidic cleans, weekend dismantling of equipment, cleaning and disinfection of chillers and sanitation of surfaces, fixtures and fittings above 2 metres.

### **9.9.11 Clean the cleaning equipment**

Following their use for cleaning, cleaning equipment should itself be cleaned and disinfected. Cleaning equipment should be visually checked for

damage and any areas where microorganisms could reside, or loose parts which might become a foreign body hazard, should be replaced. Cleaning equipment should be stored in racks to dry or kept in disinfectant solution until their use is required.

A sanitation sequence should be established in a processing area to ensure that the applied sanitation programme is capable of meeting its objectives and that cleaning programmes, both periodic and for areas not cleaned daily, are implemented on a routine basis. In particular, a sanitation sequence determines the order in which the product contact surfaces of equipment and environmental surfaces (walls, floors, drains etc.) are sanitised, such that once product contact surfaces are disinfected, they should not be re-contaminated.

Based on industrial case studies, the following sanitation sequence for RTE food production areas has been demonstrated to be useful in controlling the proliferation of undesirable microorganisms. The sequence must be performed at a 'room' level such that all environmental surfaces and equipment in the area are cleaned at the same time. It is not acceptable to clean and disinfect one line and then move onto the next and start the sequence again as this merely spreads contamination around the room.

1. Remove gross soil from production equipment.
2. Remove gross soil from environmental surfaces.
3. Rinse down environmental surfaces (usually to a minimum of 2 m in height for walls).
4. Rinse down equipment and flush to drain.
5. Clean environment surfaces, usually in the order of drains, walls then floors.
6. Rinse environmental surfaces.
7. Clean equipment.
8. Rinse equipment.
9. Disinfect equipment.
10. Rinse equipment (if required).

## **9.10 Evaluation of sanitation effectiveness**

Assessment of the effectiveness of the sanitation programme's performance is part of day-to-day hygiene testing and, as such, is linked to the factory environmental sampling plan. The control of the environmental routes of contamination is addressed via the development of a thorough risk analysis and management strategy, typically undertaken as part of the factory prerequisite study (Holah *et al.*, 2011), resulting in the development of the factory environmental sampling plan (see Chapter 16).

Environmental sampling is directly linked with both process development and product manufacture and as such, has three distinct phases. The

performance of the sanitation programme is an important aspect of due diligence and is assessed by monitoring to check sanitation process control, and verifying the sanitation programme success. Monitoring is a planned sequence of observations or measurements to ensure that the control measures within the sanitation programme are operating within specification and are undertaken in a time frame that allows sanitation programme control. Verification is the application of methods in a longer time frame to determine compliance with the sanitation programme's specification.

Monitoring the sanitation programme is via physical, sensory and rapid chemical hygiene testing methods. Microbiological testing procedures are never fast enough to be used for process monitoring. Monitoring of sanitation programmes can take place prior to their commencement and can include, for example, availability and condition of cleaning equipment, availability of cleaning operatives, chemicals withdrawn from stores in stock rotation and a sufficient time window to complete chemical sanitation tasks. Within sanitation programmes, monitoring can include, for example, detergent and disinfectant temperatures; chemical concentrations; surface coverage of applied chemicals and measurement of detergent/disinfectant contact time.

The primary monitoring of any cleaning programme efficacy is 'visual' cleanliness and involves the assessment of a surface as being free from food debris and other soiling by a person without any sampling aids (other than perhaps a torch). This may involve looking at the surface, feeling the surface for any signs of 'invisible' deposits such as grease and oils, and even smelling the equipment. Not all surface materials will necessarily clean to the same degree and not all surfaces will be 'visible'. Dismantling may be needed to establish that all appropriate surfaces have been visibly cleaned. As well as freedom from soiling, visual inspection should also establish freedom of any other hazards attributed to the cleaning programme. Primarily these are related to cleaning fluids and foreign bodies. Cleaning fluids may be hazards in their own right, particularly in their concentrated form, or when diluted, may become a nutrient and water source to aid residual microbial growth. Inspection should therefore concentrate on the identification of any undrainable surfaces or other areas in which liquids could be contained. Foreign bodies may arise from cleaning equipment such that rough or sharp equipment surfaces may cause the entrapment of brush bristles or the disintegration of cleaning cloths/pads.

If surfaces are not visually clean, no use of any other monitoring or verification method is appropriate, as the surfaces are visually dirty.

Rapid hygiene monitoring methods are methods which are more sensitive than visible assessment and whose results are generated within a time frame (usually regarded as within approximately 10 minutes) sufficiently quickly to allow process control. Current methodology allows the quantification of microorganisms (ATP), food soils (ATP, protein) or both (ATP) (see

Chapter 16). No technique is presently available which will allow the detection of specific microbial types within this time frame.

Many food processors typically use the rapidity of ATP detection to allow monitoring of the cleaning operation such that if a surface is not cleaned to a predetermined level it can be re-cleaned prior to production. Similarly, equipment can be certified as being cleaned prior to use in processing environments where kit is quickly reused or when a manufacturing process has long production runs. Some processors prefer to assess the hygiene level after the completion of both the cleaning and disinfection phases, whilst others monitor after the cleaning phase and only go on to the disinfection phase if the surfaces have been adequately cleaned.

Verification of the sanitation programme's performance is usually undertaken by microbiological methods, though ATP levels are also used (especially in low risk). Microbiological sampling is typically for the total number of viable microorganisms remaining after cleaning and disinfection, i.e. TVC or indicator microorganisms, as a measurement of the ability of the sanitation programme to both control all microorganisms and maximise microbial detection. Sampling targeted at specific pathogens or spoilage organisms, which are thought to play a major role in the safety or quality of the product, is undertaken to verify the performance of the sanitation programme designed for their control. The use of TVC is applicable to both low- and high-risk processing areas though detection of specific pathogens should be undertaken in high risk only. Microbiological assessments have also been used to ensure compliance with external microbial standards, as a basis for cleaning operatives' bonus payments, in hygiene inspection and troubleshooting exercises, and to optimise sanitation procedures.

In relation to microorganism numbers, it is difficult to suggest what is an 'acceptable' number of microorganisms remaining on a surface after cleaning and disinfection as this is clearly dependent on the food product, process, 'risk area' and degree of sanitation undertaken. There is also no European legislation that describes a microbiologically clean surface. A number of figures have been quoted in the past (as TVC per square decimetre) including 100 (Favero *et al.*, 1984), 540 (Thorpe and Barker, 1987) and 1000 (Timperley and Lawson, 1980) for dairies, canneries and general manufacturing respectively. The results in Table 9.1 show that in chilled food production and where starting microbial counts are in the order of  $>10^6$  per swab, sanitation programmes should achieve levels of around 1000 microorganisms per swab, which on flat surfaces approximately equates to a square decimeter. Expressing counts arithmetically is always a problem, however, as single counts taken in areas where cleaning has been inadequate (which may be in excess of  $10^8$  per swab) produce an artificially high mean count, even over thousands of samples. It is better, therefore, to express counts as log to the base 10, a technique that places less emphasis on a

relatively few high counts, and Table 9.1 shows that mean log counts of approximately 1 should be obtained.

Because of the difficulty in setting external standards, it is best to set internal standards as a measurement of what can be achieved by a given sanitation programme. A typical approach would be to assess the level of microorganisms, ATP or protein present on a surface after a series of 10 or so sanitation programmes in which the sanitation programme is carefully controlled (i.e. detergent and disinfectant concentrations are correct, contact times are adhered to, water temperatures are checked, pressure hoses are set to specified pressures, sanitation schedules are followed, etc.). The mean result is the best that can be achieved when the cleaning programme is optimised and undertaken correctly. This is not likely to be repeatable on every occasion and the target may be set as the mean result plus 'a little bit for day to day error'. For example, if a mean ATP value of 100 RLU has been obtained, a target value for subsequent cleans could be set at 150 RLU. In some cases one target may not be appropriate and it may be necessary to set different targets for different areas of the process lines. For example, it may be appropriate to set an ATP target of 150 RLU for conveyor belt surfaces, which can be particularly difficult to clean, and a target of 100 RLU for all other surface material types. In some instances, cleaning may result in ATP or protein levels that do not differ significantly from controls, i.e. residues following cleaning are not detected. In this case these techniques are not appropriate and microbiological standards have to be adopted.

As more information is obtained from routine cleaning programme verification, the targets can then be reviewed and the food manufacturer can seek to reduce them as appropriate by changing the manufacturing environment, process, equipment or cleaning programme. A review of the target standard would also be required if any of the variables controlling the target were changed; primarily the food product or process or the sanitation programme.

## 9.11 Sanitation management

Senior management must take full responsibility for the successful operation of the sanitation programme; ultimately, failures in the programme generally reflect poor management. Three types of sanitation programmes can be implemented by management and each has its advantages and disadvantages: at the end of production, production operatives clean their workstations and then (a) they form a cleaning crew and undertake the sanitation programme; (b) a separate, dedicated cleaning gang complete the sanitation programme; or (c) cleaning and disinfection is undertaken by contract cleaners.



For the majority of food processing operations, the following is a guide to the responsibilities of senior management:

- Understand the objectives of cleaning and disinfection for a particular product and the hazards presented to the product design.
- Always seek to improve hygiene standards. Hygiene has traditionally not had the same research support as other areas of importance in food manufacture and is thus a new and developing science. It is only relatively recently that new concepts have been developed, based on scientific assessments, and management must be flexible enough to try out and to encourage such concepts when they emerge.
- Lead by example by being both always properly attired in food production areas and (occasionally) present in production areas when sanitation is being undertaken (usually in the early hours of the morning!).
- Provide the required equipment (including maintenance), the staffing levels and the time to undertake the sanitation programme effectively. Cleaning operatives should preferably be a dedicated labour pool whose priority is to sanitation (i.e. not production). Similarly, operatives should not join in the cleaning team as an 'introduction to production'.
- Management should be capable of giving praise when sanitation is undertaken correctly, as well as discipline when it is not. In companies where bonus systems have been employed based on microbiological assessments of equipment after cleaning, results have indicated that hygiene has generally been improved and bonuses are rarely missed.
- Appoint or nominate a manager to be responsible for the day-to-day implementation of the sanitation programme.

The manager who assumes responsibility for the sanitation programme must have technical hygiene expertise and, in addition to man-management and budget skills, has a range of job functions including the following:

- The selection of a suitable chemical supplier.
- The selection of sanitation chemicals, equipment and methods.
- The training of cleaning operatives.
- The development of cleaning schedules.
- The implementation of sanitation programme monitoring systems.
- Representation of hygiene issues to senior management.

It is essential to have strong links with a chemical supplier who should be able to do much more than simply supply detergents and disinfectants. They should be chosen on their abilities to undertake site hygiene audits, supply suitable chemical dosing and application equipment, undertake operative training and help with the development of cleaning schedules (by trials) and sanitation monitoring and verification systems. Good chemical companies respond quickly to their customer needs, periodically review their customers' requirements and visit during sanitation periods to

ensure that their products are being used properly and are working satisfactorily. The level of expected service from the chemical supplier should be agreed between the chemical supplier and food manufacturer and be documented as a specification, as for any other product or service purchased by the food manufacturer. The cleaning manager may also need to visit the chemical supplier's site to audit their manufacturing and quality systems.

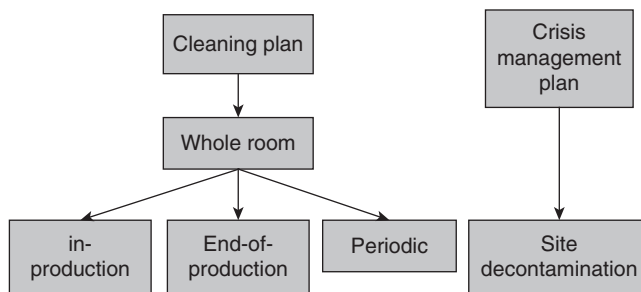
When new equipment is purchased or processing areas are designed or refurbished, insufficient attention is usually placed on sanitation requirements. Equipment or areas of poor hygienic design will be more expensive to clean (and maintain) and may not be capable of being cleaned to an acceptable standard in the time available. If improperly cleaned, adequate disinfection is impossible and thus contamination will not be controlled. Hygiene management must be strongly represented, thus ensuring that hygiene requirements are considered alongside those of engineering, production and accounts, etc.

Whilst in theory systems and/or chemicals could seem appropriate for the required task, every factory, with its water supply, food products, equipment, materials of construction and layout, etc., is unique. All sanitation chemicals, equipment and methods must, therefore, be validated in the processing environment. New products and equipment are always being produced and a good working relationship with hygiene suppliers is beneficial. Only disinfectants that have been approved to the relevant European Standards should be used.

The cleaning operative's job is technical and potentially hazardous, and all steps should be undertaken to ensure that sufficient training is given. By the nature of the job, training needs to be comprehensive and should include the following:

- A knowledge of basic food hygiene.
- The importance of maintaining low-/high-risk hygiene barriers during cleaning.
- The implications to product safety/spoilage of poor sanitation practices.
- An understanding of the basic function and use of sanitation chemical and equipment and of their sequence of operation.
- A thorough knowledge of the safe handling of chemicals and their application and the safe use of sanitation equipment.

The components of a management system for a sanitation programme are described in Middleton and Holah (2007) and shown schematically in Fig. 9.5. The cleaning plan should list all the cleaning and disinfection tasks that need to be undertaken across the food manufacturing site and their frequency (daily, weekly, monthly, etc.). It is primarily used to describe and record all of the cleaning tasks that need to be undertaken each day. The plan incorporates the cleaning of all manufacturing areas including processing equipment and utensils, ancillary equipment, services, cleaning



**Fig. 9.5** Schematic contents of a documented management system to undertake cleaning and disinfection tasks.

equipment, personal equipment (e.g. boots and chain mail gloves) and the environment. In some cases that plan may include cleaning of outside areas of the site, laundering of air socks and laundering of staff clothing.

Cleaning schedules are the written work instructions that detail precisely how the cleaning and disinfection procedures for each task should be undertaken. The cleaning schedule can also be used as the work instruction against which cleaning operatives can be formally trained. In addition, cleaning schedules can also be used to describe the cleaning and disinfection process to interested parties (e.g. internal and external auditors) who may be visiting the premises during a time period in which cleaning and disinfection procedures are not taking place.

The 'whole room' cleaning schedule focuses on two key parameters. The first details all the requirements for the practical management of the cleaning and disinfection operation and includes manpower, any specialist engineering support, equipment, chemicals and their dosing, health and safety, room preparation, protection of any food production operations, how cleaned surfaces are protected from recontamination, how the room is prepared for subsequent production and how the cleaning equipment itself is cleaned and maintained. The second details requirements to maximise the removal of microorganisms from the processing area (rather than simply redistributing them) and to leave the food contact surfaces as free of microorganisms as possible for subsequent food production. This encompasses both the sanitation sequence (Section 9.9) and detailed instructions on each individual cleaning operative's task and how they are going to be coordinated with their colleagues to ensure the production area is cleaned as a unit.

During production periods, 'Clean as you go' operations should always be undertaken as they encourage hygienic work practices, help prevent slip and trip accidents and may be motivational to food production operatives. The nature of the cleaning methods used, however, may be very different from those used at the end of production. Consideration should be given

to how such cleaning could cross-contaminate other processing lines that may be in production. The use of screening to minimise cross-contamination may be appropriate. Restriction of the use of water is encouraged wherever possible to prevent microbial growth on production surfaces. Any major spillages during production should always be thoroughly cleaned to prevent the growth of microorganisms on processing surfaces, which may become a significant challenge to the subsequent end-of-production sanitation programme.

End-of-production cleaning schedules can be written for all equipment in a room (particularly if the equipment is simple and does not need dismantling), for individual pieces of equipment (particularly if the equipment is complex and requires extensive isolation and dismantling), ancillary equipment, services, items of personnel protective equipment and the processing environment. The following are typical features that may be contained in schedules:

- Name of the processing area or item of equipment, etc., to be cleaned.
- Number of cleaning operatives required. For some specific equipment this may include named individuals who have been specifically trained with respect to the dismantling, safety or reassembly of the equipment.
- List of all personal protective equipment (PPE) required.
- Requirement for equipment isolation and dismantling prior to cleaning, which may require additional operatives or specialist engineering support.
- List of cleaning equipment required.
- List of cleaning chemicals to be used and their in-use concentrations, contact times and temperatures.
- Detailed work instruction describing the method and scheduling of chemical and rinse application including guidance timings.
- Following cleaning and/or disinfection, identification of key inspection points used to monitor programme success.

The need for periodic cleaning practices has been mentioned earlier (Section 9.2). Periodic cleaning schedules can be developed to combine periodic cleaning tasks on a range of equipment (typically a 'weekend' cleaning schedule) or can be added to the 'end-of-production' cleaning schedules if they are detailed for individual items of equipment.

A site decontamination plan may be associated with the company Crisis Management Plan, detailing a planned decontamination of the processing areas (usually the high-hygiene zone) following a potential pathogen contamination incident to allow production to re-start as appropriate. Decontamination of the processing area describes cleaning and disinfection practices beyond end-of-production and periodic cleaning and typically involves removing and disposing of all food and packaging materials, further (total) dismantling of routine equipment, dismantling of ancillary equipment

(e.g. evaporative condensers, air socks, air supply ductwork) and the wider use of usually stronger disinfectants.

## 9.12 Conclusion

Much of cleaning and disinfection is historical and has seen little change in terms of the chemicals and methods adopted. In many ways the advances in sanitation methodology have not kept pace with the innovations in food products. For much of the food industry sanitation programmes are effective and well controlled but for RTE products, and for the dry goods sector in particular, dry cleaning has not been developed and there is a real need for advances in this area to combat issues with, for example, *Salmonella* and *Cronobacter*. In the chilled RTE sector, sanitation is now better managed and scheduled, but the emphasis remains on the food contact surfaces rather than the whole processing environment. The concept of the survival and persistence of pathogens (e.g. *Listeria*) in RTE facilities will require the further development of wholeroom disinfectant techniques to ensure that facilities can effectively control such persistent microbiological challenges.

## 9.13 References

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## Cleaning in place (CIP) in food processing

**F. Moerman, Catholic University of Leuven – KU Leuven, Belgium,  
P. Rizoulières, Boccard Food, France and  
E. A. Majoor, formerly Unilever R&D Vlaardingen, The Netherlands**

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**Abstract:** To clean process equipment cost effectively without the need for any disassembly and reassembly, cleaning in place (CIP) is commonly applied in the food industry. Owing to the high degree of automation, CIP systems provide consistent and reproducible cleaning and allow full traceability of the cleaning operations. This chapter provides food manufacturers with the information needed to understand and improve the in-place cleaning of their food processing equipment. An overview is given of the detergents and disinfectants available, the most optimal conditions (temperature, detergent concentration, flow rate and water quality) for cleaning, and the most optimal CIP system designs allowing cleaning without contamination of food products. To optimize the cleaning of tanks that are commonly found in many food processing lines, guidance is given on the hygienic design and drainability of these tanks, the properties of the tank cleaning devices available, their necessary number and most optimal location, and the amount of cleaning solution required.

**Key words:** cleaning in place (CIP), tank, detergent, mixproof, cleaning device.

### 10.1 Introduction

#### 10.1.1 Definition of cleaning in place (CIP)

Cleaning in place (CIP) is an automatically performed method of cleaning, applied to remove residues from complete items of plant equipment and pipeline circuits without dismantling or opening the equipment. It is a system of cleaning engineered to provide fast, productive, consistent and reproducible high-quality cleaning of all product contact surfaces to a predetermined level of cleanliness. The system works by circulating chemical (detergent and disinfectant) solutions and rinsing water through food production equipment (tanks and piping) that remains assembled in its

production configuration and by jetting or spraying the product contact surfaces under conditions of increased turbulence and flow velocity (Majoor, 2003; Moerman, 2003).

### **10.1.2 Main advantages/disadvantages of CIP**

CIP has been widely applied in dairy, brewery, food and wine processing for more than 50 years, because food manufacturers quickly realized that CIP is, overall, more advantageous (compare Tables 10.1 and 10.2) (Christi, 1999; Majoor, 2003; Moerman, 2003).

## **10.2 Cleaning chemicals and disinfectants for cleaning in place (CIP)**

### **10.2.1 Cleaning chemicals**

A cleaning process consists of three main steps: (1) displacement of organic and/or inorganic soil from the equipment substrate using chemical reactions and physical processes, (2) dispersion of the soil into the cleaning medium and (3) prevention of soil re-deposition on the substrate. The first step requires a cleaning agent with excellent wetting power to reduce the surface tension of the cleaning medium and to help the cleaning liquid to penetrate into the soil and surface pores. The solubilization of the soil can be increased by using different detergents to disperse and sequester organic and inorganic soil. The second step requires detergent chemicals with excellent suspending and emulsifying power to bring the insoluble soils into suspension and to keep oils and fats dispersed within the cleaning solution. Finally, to prevent re-deposition of the soil, the dispersing and sequestering properties involved in the first and second step must be long-lasting.

Because no universal detergent formulation exists, a detergent should be selected that provides the best cleaning results for a specific type of soil. The selection of a suitable cleaning agent is a demanding task, because it must meet several criteria, including:

- being effective against a wide range of soils;
- excellent wetting, fat emulsification and sequestration properties;
- potential to bring soil into suspension and keep it dispersed within the cleaning solution;
- optimal cleaning at low concentration;
- fast and complete solubility in water;
- excellent hard water tolerance;
- low-foaming to allow fast and complete rinsability with no detergent residues left;
- food grade properties: non-toxic, free of perfumes and dyes, etc.;
- safe to use and authorized by regulations;
- compatible with all materials of construction, non-corroding;

**Table 10.1** Advantages of CIP systems (Christi, 1999; Majoor, 2003; Moerman, 2003)

Advantages	More specific ...
Suitable to clean a broad selection of process equipment	Cleaning of tanks, pipelines, pumps, valves, heat exchangers, centrifugal machines and homogenizers, etc.
Minimum manual effort	Manual operations can be reduced or eliminated entirely depending upon the degree of automation.
Easy to automate	Consistent and reproducible high-quality cleaning with less cross-contamination between product batches and less off-spec products because each cleaning program is the same as the previous one.
Improved hygiene	In a closed system CIP process with no human contact, higher temperatures and stronger detergents can be used for circulation, and many times more cleaning fluid per unit time and per unit area under conditions of increased turbulence and flow velocity can be applied. Fluid can be distributed more evenly, or more solution can be applied to highly soiled areas while less-soiled areas can be treated less aggressively. Because the physical integrity of the process equipment is maintained during CIP, recontamination is less likely. The overall result is fewer product rejections.
Traceability of the cleaning operations	Automated CIP systems can record all cleaning sequences and key parameters (time, temperature, chemicals and physical action), providing validation monitoring, documentation and traceability.
Reduced processing plant downtime	Tanks and pipelines can be cleaned as soon as they are empty, and in reverse they can immediately be refilled after cleaning. No time has to be spent in disassembly and reassembly of process equipment. CIP allows faster cleaning than manual cleaning.
Reduced disassembly wear and damage	The high frequency of disassembly and reassembly of process equipment components that is typical for manual cleaning operations may cause irreversible damage to their machined surfaces. As this is not the case with CIP, lower maintenance and repair costs are observed.
Lower environmental impact	Owing to partial or total recovery of cleaning solutions and rinsing waters, significant savings on water, detergent and energy consumption can be realized. The amount of effluent and the pollution load will be much lower.
Considerable cost savings	Savings on water, detergents, disinfectants, energy, effluent treatment, labour, rework of off-spec products.
Greater operator safety	CIP reduces the exposure of the operating personnel to hazardous atmospheres and cleaning conditions such as high temperatures, and aggressive cleaning agents and disinfectants. The use of ladders or temporary supports for dangerous vessel entry and the risk of falls on slippery internal surfaces are also eliminated.

**Table 10.2** Disadvantages of CIP systems (Christi, 1999; Majoor, 2003; Moerman, 2003)

Disadvantages	More specific ...
High capital cost	Investment costs for implementing CIP in a new facility or retrofitting an existing plant are high, especially because most CIP systems are custom designed. The complexity of the hardware and software to control and monitor the CIP process further increases capital expenditure. But payback of the investment is usually less than a year, due to the lower labour, raw material and energy costs
Not suitable to remove insoluble heavy soils	CIP lacks effectiveness in removal of heavy soils in the meat and poultry industry. In these areas, the application of CIP is limited to vacuum thawing chambers, pumping and brine circulation lines, pre-blend/batch silos, and edible and inedible fat-rendering systems.
Inflexibility	Stationary CIP systems only allow cleaning of adjacent process equipment at reduced operational cost. Mobile CIP units allow more flexibility, as they may cover process equipment over a larger area.
Increased maintenance	More sophisticated equipment requires more maintenance.

- no deleterious effects on the equipment surfaces;
- environmentally friendly (e.g. biodegradable);
- concentration detectable by electronic sensors;
- low cost.

Depending on the required cleaning result, which varies from physically clean through chemically clean to microbiologically clean, a broad selection of multiple-component detergent formulations are available on the market. They can be divided into three different types: alkaline, neutral or acid.

#### *Alkaline detergent formulations*

Alkaline detergent formulations are typically used to remove organic residues and commonly consist of the following ingredients (Moerman, 2003; Rohsner, 2005):

- NaOH or KOH: these have equal hydrolysis and peptization power over fat and proteins respectively. Despite its better rinsability, the use of KOH is less common due to its cost.
- Silicates, phosphates, phosphonates and citrates: 'builders' used for their suspending properties and to enhance the efficacy of surfactants in the removal of soil.

- Surface active agents: these perform many functions such as wetting, soil penetration, soil suspension, dispersion and emulsification. Furthermore, they aid in rinsing the equipment surface by reducing the surface tension. Non-ionic surfactants are most frequently used in detergent formulations, because anionic surfactants foam very quickly. Cationic surfactants have rather low detergency but high biocidal properties. Amphoteric surfactants are sometimes used as supplements to non-ionic surfactants for their microbicidal effect.
- Stoichiometric sequestrants such as ethylenediaminetetraacetic acid (EDTA), nitrilotriacetic acid (NTA) and gluconate: these work within alkaline cleaners, in strictly stoichiometric ratios, as real complexing agents, suppressing the negative impact of water hardness and improving the removal of inorganic soil.
- Threshold sequestrants such as phosphonates, polyphosphonates, polyacrylates: these are active in sub-stoichiometric concentrations. They can also prevent deposition of water scale on equipment surfaces during the rinse cycles. During rinsing, the remaining film of the cleaning solution on equipment surfaces is diluted and reduces the concentration of EDTA and NTA to such an extent that residual alkalinity on surfaces causes the surplus water hardness to precipitate.
- Hypochlorites and hydrogen peroxide: their oxidizing effect assists in the removal of tenacious and insoluble soil. However, hypochlorites may cause pitting of stainless steel and taint certain plastics.
- Corrosion inhibitors such as polysilicates, modified carbohydrates and phosphonates: these are usually added to the detergent formulation to prevent corrosion of stainless steel by detergent chemicals.
- Hydrophobic non-ionic surfactants: these work as defoamers, reducing the negative impact that foaming has on cleaning efficiency and the time required to rinse the equipment free of detergent.
- Hydrotrophic substances: these stabilize liquid formulations at high or low temperatures.

#### *Neutral detergent formulations*

Neutral cleaners are used in circumstances where NaOH and KOH-based detergents would have a corroding effect, e.g. on aluminium, galvanized and other soft metal surfaces. To obtain a neutral pH of 6–8, NaOH and KOH are replaced in these cleaners. Neutral detergent formulations may contain the following components (Moerman, 2003; Rohsner, 2005):

- Phosphates, phosphonates and citrates: these give mild alkalinity and buffering capacity to the cleaning solution. They are also very effective in removing heavy soil without risking bloom formation and corrosion, which typically occurs with caustic alkalis as they are gradually converted to carbonates. Their wetting power, soil lifting power, dispersion and



emulsification power are superior to NaOH and KOH. However, they are more expensive.

- Non-ionic or anionic surfactants: these allow soil penetration, soil emulsification and surface wetting, and have low surface tension. Non-ionic surfactants are preferred over anionic surfactants, because of the foaming caused by the latter.
- Enzymes such as proteases, lipases and amylases may remove tenacious protein deposits, fat (in the absence of surfactants) and starch respectively. Enzyme-based cleaning products are commonly used for the cleaning of membrane filtration equipment because they are less aggressive than more common detergents. They have also proven valuable in the cleaning of plate and tube heat exchangers. However, as enzymes are sensitive to heat, the temperature of the cleaning solution must be limited and, as they are proteins, they will increase the nitrogen load of the effluent water and therefore require a more specialized wastewater treatment infrastructure.
- Hydrotrophic substances: these can stabilize liquid formulations at high or low temperatures.

#### *Acid detergent formulations*

Mineral deposits on equipment are nearly impossible to remove with alkaline cleaners, and, to varying degrees, an alkaline cleaner may even contribute to a mineral deposit. Hence, an acid cleaning cycle is required to dissolve mineral salts or to remove scale formed after the alkaline cleaning cycle. In the fermentation and brewery industry, CIP processes mainly use acid cleaning practice. This is because the CO<sub>2</sub> generated during the fermentative process will rapidly break down NaOH and KOH to Na<sub>2</sub>CO<sub>3</sub> and K<sub>2</sub>CO<sub>3</sub> respectively. These sodium and potassium carbonates can then quickly precipitate as process-generated scale. Further, the loss of CO<sub>2</sub> can create a sudden underpressure within the fermenter, increasing the risk of vessel implosion.

An acid-type detergent needs to produce a pH of 2.5 or lower in the final use solution, work well in both hard and soft water and cause as little corrosion on metals as possible. Acid detergent formulations are typically blends of inorganic acids, organic acids or acid salts, usually with the addition of other ingredients (Moerman, 2003; Rohsner, 2005). These are listed below.

Inorganic acids, such as nitric, sulphuric, sulphonc and phosphoric acid have high acidic strength but are often corrosive, potentially dangerous to work with (irritating to skin, eyes, etc.), injurious to clothing and can precipitate some soluble salts.

1–2% nitric acid cleaning solutions can remove inorganic residues such as scale, milk stone and beer stone. They are used to clean and demineralize heat exchangers and evaporators, although nitrous vapours can pose risks of skin burns and hamper operators in their work. Due to its oxidizing

properties at higher concentrations,  $\text{HNO}_3$  cannot be used in more complex formulations, e.g. with surfactants. Moreover, nitrates contribute to the eutrophication of the surface water.

In its raw form, sulphuric acid is corrosive to stainless steel and must therefore be formulated with a corrosion inhibitor.  $\text{H}_2\text{SO}_4$  in a 1% solution is the cheapest source of acidity, but its inherent detergency is poor, making it not cost effective. The application of  $\text{H}_2\text{SO}_4$  in cleaning practices must also be limited to  $40^\circ\text{C}$ .  $\text{H}_2\text{SO}_4$  is used in some sanitizer formulations in which the low pH is a prerequisite for effective use of the biocide present. The major drawback of  $\text{H}_2\text{SO}_4$  is that the sulphates contribute to the salt load of the effluent, and, under aerobic conditions, high levels of sulphate cause physical damage to the concrete walls of the wastewater treatment plant. Water purification plants with an anaerobic treatment step can also give rise to  $\text{H}_2\text{S}$  formation, even at low sulphate concentrations. Hence, phosphoric acid or organic acid are more commonly used in cleaning solutions.

Phosphoric acid is effective, but, when frequently used, a significant increase in the phosphorus wastewater load can occur. Many countries require supplementary taxes per unit of phosphorus wasted in the environment, because of the resulting eutrophication. As few food-processing companies have a P-removal step available in their wastewater treatment plant, organic acids should be used instead of phosphoric acid.

Sulphamic acid is frequently used for removal of rust and limescale. Compared with most of the common strong mineral acids, sulphamic acid has desirable water descaling properties, low volatility and low toxicity. It is a water-soluble solid that may form soluble calcium and iron-III salts. Although it is less corrosive, corrosion-inhibitors are still required.

Organic acids such as formic, acetic, citric, tartaric, lactic and gluconic acid are much less aggressive than mineral acids. They are also less corrosive, less dangerous and are generally accepted in food practice because they are mentioned on the 'positive' EU food additives list with an E-number. However, they will increase the chemical oxygen demand (COD) load of the wastewater. Although the acids themselves are quite biodegradable, in large amounts they can affect the breakdown of wastewater effluents, rich in organic material, which are of low degradability. In most cases, however, these problems are actually due to the insufficient treatment capacity of the wastewater plant due to a lack of the oxygen supply needed for the degradation of the waste load.

Sulphonic acids, which are much stronger than the corresponding carboxylic acids, can be used instead. They are usually soluble in water, colourless and non-oxidizing and exhibit detergent-like properties, which is convenient for cleaning food processing equipment.

An acid oxidising agent that is regularly used in cleaning practices, is peracetic acid (PAA). PAA is non-foaming, and effective both as a detergent and disinfectant. However, it has an irritant smell, may attack rubber

gaskets, and may cause corrosion. Moreover, a PAA load that is too high can cause effluent treatment problems, due to its destructive impact on the biomass in the wastewater treatment plant.

Other ingredients that can be added include the following:

- Non-ionic or anionic surfactants: these provide cleaning efficacy in the case of organic soil, enhance scale-removing properties and are used for removing fat residues.
- Corrosion inhibitors like phosphonic acids: these are added to prevent the corrosion of stainless steel.
- Hydrophobic non-ionic surfactants, which work as defoamers.
- Hydrotrophic substances.

### 10.2.2 Disinfectants

Disinfection aims to reduce the number of food spoiling microorganisms (responsible for off-colours, off-flavours and off-odours) and pathogens that may be present on process equipment after cleaning. For the disinfection process to be successful, process equipment surfaces have to be cleaned to a sufficient level to remove soil residues, which would reduce the efficacy of disinfectants. The disinfectants must be correctly applied to the equipment surfaces, following the prescribed procedure and in the correct amounts. Chemicals used in disinfectant formulations (Roshner, 2005; Rizoulières *et al.*, 2009) include the following:

- Oxidizing disinfectants (hypochlorites, iodophores, ozone, peracetic acid, hydrogen peroxide), whose oxidizing activity kills microorganisms.
- Non-oxidizing disinfectants (quaternary ammonium compounds, ampholytes, alcohol) that kill or inactivate microorganisms by non-oxidative complex reactions on either the outside or inside of the microbial cell. Formaldehyde and phenolics are very effective but they are toxic, irritating and cause off-odours. Quaternary ammonium compounds should not be used as they cause foaming.
- Buffering agents (bases, acids or salts) are used to provide the optimum pH required for the biocide to be active, to control the corrosion risk typical of oxidizing disinfectants or to provide the necessary stability to the disinfectant in solution or concentrated form.
- Non-ionic or anionic surfactants improve surface wetting or enhance foam applications.

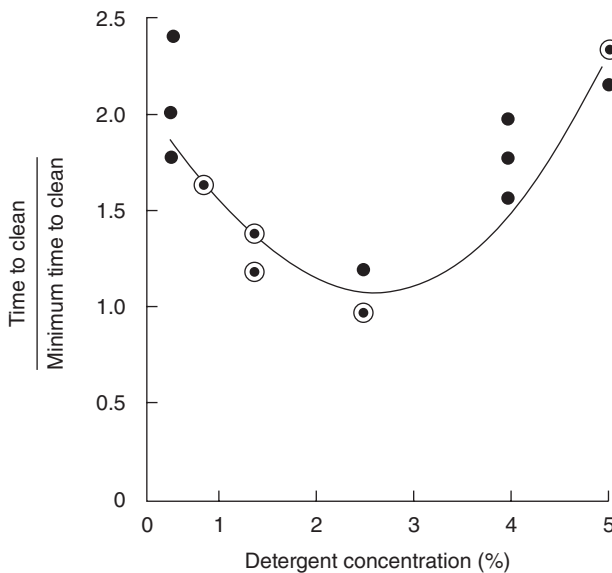
## 10.3 Other key factors for an effective CIP process

To clean all process equipment and piping systems in the shortest time possible, a CIP system aims to combine the benefits of the chemical activity of the detergent chemicals (chemical energy) and high temperature of the

cleaning solution (thermal energy) with the mechanical action caused by the turbulent flow and impact of the sprays/jets of cleaning solution on the equipment surfaces (mechanical energy). However, other factors are equally important to successful CIP. These include the quality of the water used to prepare the cleaning solutions (low counts of spoilage microorganisms, low water hardness), the intimate contact between the cleaning solution and soiled surface (all surfaces to be cleaned must be covered), the applied CIP programme, the hygienic design of the process equipment to be cleaned and the quality of the work of the cleaning staff.

### 10.3.1 Detergent concentration

The detergent concentration must be set depending on both the type of soil and the most difficult to clean part of the processing line or process equipment. For removal of milk deposits from the heated surfaces of a plate heat exchanger, Timperley and Smeulders (1988) obtained the best results with a detergent concentration of 2.5% (Fig. 10.1). They demonstrated that increasing the detergent concentration above 2.5% w/w increases the cleaning time. It is important to monitor the strength of the detergent solution, especially in a reuse system, because high detergent concentrations (i.e. above 2–3%) are often not economic. The concentration of the chemicals which determine detergency, should be controlled either manually or automatically.



**Fig. 10.1** The effect of the detergent concentration on the cleaning time (Timperley and Smeulders, 1988).

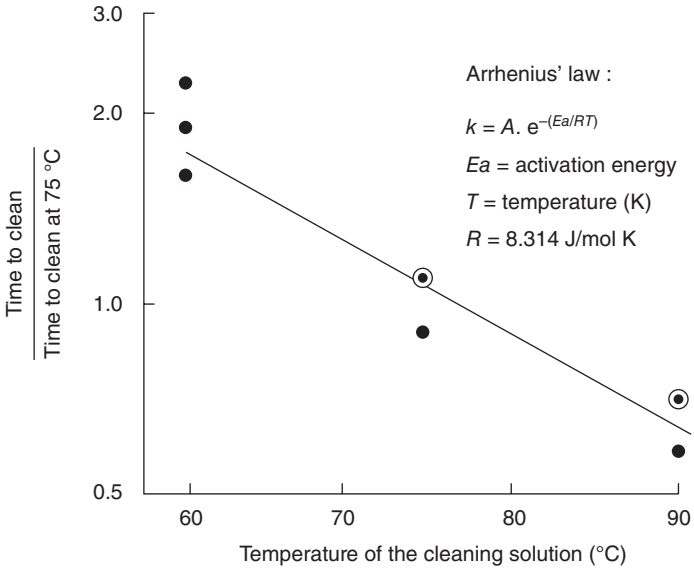
As general recommendations, about a 1% caustic soda solution is sufficient for cleaning storage tanks, pipelines and fermentation tanks, 1–2% for cleaning multi-purpose tanks and plate heat exchangers and 2–3% for cleaning ultra-high temperature (UHT) plants. However, up to 5% may be necessary to clean heavily soiled equipment (Timperley & Smeulders, 1988). Acid solutions are normally used in the region of <1%, since at higher concentrations corrosion of metal surfaces may occur (Majoor, 2003).

### 10.3.2 Temperature

Timperley and Smeulders (1988) have demonstrated that the natural logarithm of the cleaning time is inversely proportional to the absolute temperature of the solution (Fig. 10.2). In the Arrhenius equation the logarithm of the reaction rate is also inversely proportional to the absolute temperature, meaning that the higher the temperature of the detergent solution, the more effective its cleaning action.

It is important to maintain the cleaning solution in the CIP return line at a sufficiently high temperature to avoid re-deposition of soil in this line. A CIP system must keep the temperature between certain values during all stages of the cleaning process.

While manual cleaning must be carried out at a maximum of 45–50°C, CIP cleaning may well take place at 85–90°C. Higher temperatures (e.g.



**Fig. 10.2** Cleaning time as a function of the cleaning solution temperature (Timperley and Smeulders, 1988).

100–105°C) are used during the alkaline wash of a UHT plant. Notice, however, that too high temperatures may negatively impact the physical and chemical stability of the target soil, resulting in the formation of a tenacious dirt film. Many proteins are denatured at temperatures above 80°C and even potentially at much lower temperatures, resulting in difficult to remove films. Acid treatments are usually conducted at around 60–70°C. Because an enzyme-based detergent would tend to become useless at too high temperatures, an enzymatic CIP solution must not be heated beyond 55°C (Majoor, 2003).

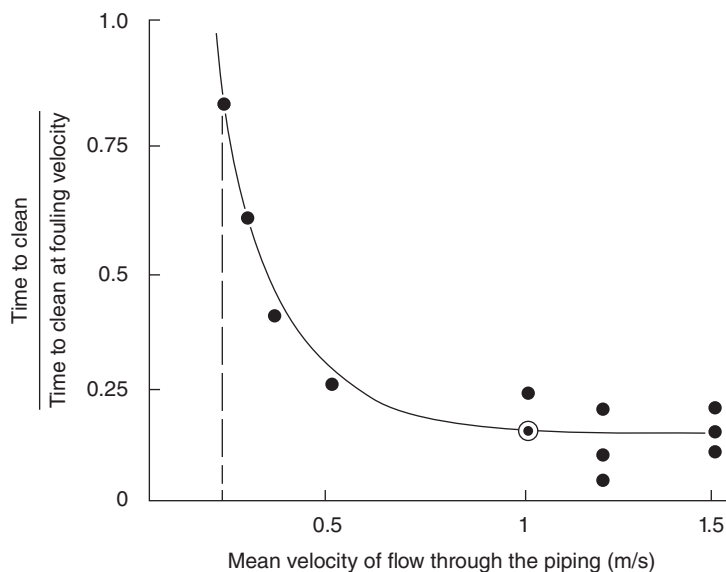
### 10.3.3 Mechanical effect of fluid flow and impact

#### *Mechanical effect of fluid in piping*

The actual cleaning mechanisms within the CIP circuit are divided into the cleaning of pipelines (and other items submersed in the cleaning fluids) and the cleaning of vessels. Pipelines are cleaned by circulating the cleaning fluids at a velocity that results in a scouring action on the pipe walls. The flow characteristics of a liquid in a pipe can be either laminar ( $Re < 2000$ ), transitional ( $Re$  2000–4000) or turbulent ( $Re > 4000$ ), and are influenced by factors including pipe diameter, fluid momentum and fluid viscosity. If the velocity is too low, a laminar flow pattern results through the pipe, limiting the interaction between the cleaning solution and the soiled surface and thus reducing cleaning potential. Hence, the effectiveness of the cleaning operation can be improved by increasing the velocity of the solution.

The cleaning time of a plate heat exchanger was found to be reduced by almost 90% when the flow rate was increased from 0.2 to 1.5 m/s (Fig. 10.3) (Timperley and Smeulders, 1988). However, the main reduction of about 70% in cleaning time is actually obtained for an increase in velocity from 0.2 to 0.5 m/s. After 0.5 m/s, the rate of improvement decreases with increasing flow rate, with an asymptote occurring at around 1.5 m/s. If we consider a tee with a pocket ratio of 1.12 (corresponding to the recommended maximum length of 28 mm for a tee with pipe diameter of 25 mm) and consider a flow of 0.2 m/s as the minimum required to start soil removal during a CIP process (Timperley and Smeulders, 1988), then the required flow in the main pipe should be at least 1.35 m/s. For many years, this figure of 1.5 m/s has been widely quoted as the target design value throughout the whole of the pipeline system. In principle, higher flow rates than 1.5 m/s do not give better cleaning results. Further if the flow rate is too high, this can result in ‘pipe hammer’, which may damage equipment, particularly the seals.

The design and operation of a CIP system therefore needs to ensure a target velocity of at least 1.5 m/s for the passage of cleaning fluids. It is impossible to control the fluid velocity in parallel pipelines fed by the same



**Fig. 10.3** Cleaning time as a function of the mean velocity of cleaning liquid through pipelines (Timperley and Smeulders, 1988).

pump so parallel flows in line-cleaning circuits must be avoided. When vessels and pipework are cleaned simultaneously, for example, the right velocity must be able to be obtained to effectively clean piping downstream of a tank. A tank can first be cleaned by spray balls, after which it can be partly filled with the cleaning liquid to create a sufficient buffer for subsequent line-cleaning. For larger-scale and more complex systems, tanks and pipes are often cleaned by individual cleaning circuits because such lines require a higher throughput to obtain the required 1.5 m/s linear velocity.

When deciding the size of the CIP supply pump, it is important to consider that the pump has to overcome pressure loss in the pipe system resulting from friction loss in the pipe itself, elbows and tees, as well as any installed equipment or instruments. When pipes with different diameters are combined in a system, one must calculate the flow velocity for each pipe as well as compensating for varying pressure losses.

#### *Mechanical effect of fluid in vessels*

For spray ball cleaning of tanks, simultaneous cleaning of tanks is possible, provided that the spray balls give a significant back-pressure. The CIP supply pump must therefore have the required capacity for this. Ordinarily for tank cleaning, a capacity of approximately 10 m<sup>3</sup>/h per tank is sufficient. At the outlet of the tank to be cleaned, a CIP return pump should have at least the same or preferably a 25% higher capacity.

### 10.3.4 Time

In general, the longer the CIP process goes on, the better the cleaning result. However, there is a certain length of time beyond which the additional increase in effectiveness is very little, while also taking up valuable production time. Since relatively high volumes of solution must be applied to soiled surfaces for periods of time ranging from as little as 5 min to as much as 1 h, recirculation of the cleaning solution is essential to remain economic.

It is very difficult to estimate the required length of cleaning time. It depends on many factors including the structure of the soils, the level of clogging, the type of equipment that is being cleaned, the characteristics of the detergents and their concentration, the temperature of the cleaning solution, the velocity of cleaning solution in pipelines and the impact of the spray/jets of cleaning solution on the equipment surface. Moist product residues of soil are easier to remove than tenacious films formed when the product is burned or dried onto the equipment surfaces. If process operations are performed at too high a temperature and if there is a long period of time before starting the CIP process, product cohesion (soil–soil bonds) and adhesion (soil–surface bonds) are increased. As a result, the factor energy in the Arrhenius equation to overcome these higher cohesion and adhesion forces has to be increased, so that more chemical, thermal and mechanical energy must be supplied and thus longer cleaning times will be required. In practice, a complete validation testing procedure may allow one to determine the suitable contact and rinsing times required to clean each part of the equipment. However, the quickest way is by carrying out visual inspections on some critical parts of the process equipment (elbows, tees, etc.) at the end of the cleaning cycle (Majoor, 2003).

### 10.3.5 Applied CIP programme

Although there exist standard cleaning programmes for each food and beverage industry type, there is no universal cleaning programme that can be used in all companies active within the same food sector, even if a process line is similar to one found in another factory. A simple process aid such as the water used in the CIP operation may give completely different cleaning results, even when the same CIP installation, CIP variables and CIP programme are applied. Worldwide, water hardness is usually different in several regions, and if that water is not treated to the same degree, a different level of cleanliness will be observed. Also, each process line or component in a food and beverage factory can have different CIP requirements. For example, the CIP requirements differ in open systems (e.g. vessels) and in closed systems (e.g. pipes).

The cleaning parameters (detergent type and concentration, temperature, flow rate, etc.) and CIP programme (sequence of cleaning and rinsing steps, duration of each step) used largely depend on the type of soils to be



removed and must be determined experimentally. If a selected cleaning programme gives an appropriate level of cleanliness, only then should the limitations of temperature, time or cleaning chemical cost be considered and adjusted accordingly. Although many variations exist, the following sequence is a typical CIP programme for a reuse CIP system, and may be considered as a guide to start up CIP trials for a given food processing line.

#### *Product flush*

A pre-flush operation is applied to remove or recover process fluid, to reduce the soil load prior to cleaning and to reduce the volume of (pre-) rinse water required. A pre-flush operation is often done using a process gas/compressed air blow, a pig, or eventually water (if allowed). In older process installations, purging the tanks and pipelines before the start of a cleaning cycle with a blast of oil-free compressed air is a convenient method of evacuating residual product from the plant. The duration of the purge and the volume of air required to completely empty the pipeline must be sufficient to flush all soiled process paths clear.

#### *Pre-rinse*

The pre-rinse uses either a fresh, clean, cool (25 °C) potable water source, or reuses the intermediate or final rinse water (slightly alkaline, often warm, with temperatures up to 45 °C) from the previous cleaning cycle. The pre-rinse is used to remove 90–95% of the gross and loosely adherent organic fat, carbohydrate or proteinaceous soil prior to the formulated alkaline wash. The pre-rinse water can be recirculated for a certain time but it is usually not desirable to introduce excessive soiling into the pre-rinse water tank. Generally the pre-rinse step is ‘once through’, which means that the pre-rinse water, once soiled, is immediately drained away, often by purging with food grade compressed air or a process gas. The pre-rinse step usually lasts 3–10 min, and is complete when the effluent runs out clear.

#### *Recirculated alkaline wash*

To make up the alkaline (typically 1–3% caustic) wash, fresh or residual rinse water is heated to 55–90 °C and caustic or other detergent is added. Since relatively long contact times (10–30 min, sometimes 60 min) are required for this primary cleaning step, the cleaning solution must be recirculated for economical operation. This step normally provides the most benefit from an increase in time. It is recommended to purge the CIP circuit of this alkaline phase by means of oil-free compressed air or a process gas, in preparation for the following rinse. The caustic solution is often recycled into the caustic tank.

#### *First intermediate rinse*

This rinse uses potable water, warm or at ambient temperature, to remove residual loose dirt and alkaline cleaner and is either applied once through

or recirculated. The first intermediate rinse usually lasts 3–10 min, depending on the type of process equipment that is cleaned, and is completed once no further residual chemical is detected. This can be ascertained by monitoring pH, conductivity or using indicator. Occasionally, for heavy soils, the pre-rinse time is increased to 30 min. The rinse water is drained (e.g. by purging with food grade compressed air or a process gas), or retained for use as pre-rinse water in the next CIP cycle.

#### *Recirculated acid wash/rinse (optional)*

If necessary, an acid wash/rinse is used to neutralize residual alkaline cleaner (alkaline cleaners can form ‘films’ on equipment surfaces which are difficult to remove with a simple post-rinse with water), to solubilize remaining dirt, and to remove mineral deposits. The acid cleaning solution often uses the residual rinse fluid from the previous step, at a concentration of 0.5–2%. Solution temperatures may vary from 50 to 70 °C and cleaning times from 3 to 20 min (occasionally 30 min). For maximum recovery of the acid solution to the acid tank, the CIP circuit is often purged with food grade compressed air or a process gas.

#### *Second intermediate rinse*

Residual acid and any additional dirt loosened in the acid wash is removed with cold rinse water. This rinse may also be recirculated. If no subsequent disinfection is done, the second intermediate rinse water is often heated to permit fast drying of the equipment. This rinse is completed once no residual chemical is detected (using pH, conductivity or indicator to test this). Common rinse times are 3–10 min, and occasionally up to 30 min. The water used is usually recovered for use as pre-rinse water. Where possible, the CIP circuit should be purged by means of food grade compressed air or a process gas.

#### *Disinfection*

A chemical or heat-based disinfection step is applied to reduce the number of microorganisms on previously cleaned surfaces. Chemical disinfection usually uses fresh water at room temperature, with disinfectant chemicals injected into the water just before the CIP supply pump. The disinfectant solutions are usually recirculated at cold temperatures for 10–30 min, although warm disinfectant solutions may give better decontamination results.

If the food manufacturer has a preference for hot pressurized water sterilization, fresh water is heated by recirculation over a plate heat exchanger or by means of steam directly injected into the flow. The water used during the thermal inactivation process is either recovered or drained. The time for this hot water sterilization process (5–60 min) and the temperature of the water (70–95 °C) may vary depending on the required reduction in the number of microorganisms. For inactivation of spores,

saturated steam (not overheated and free from non-condensable gases) should be used, and temperatures should be maintained above 121 °C for at least 20 min.

#### *Final rinse (optional)*

If the process equipment underwent chemical disinfection in a previous step, as part of an aseptic process or packaging line, it must be rinsed afterwards with sterile water. No final rinse is required if the aseptic line is thermally disinfected using steam in a previous step. However, to prevent a vacuum developing in the aseptic process equipment, sterile air should replace the steam.

If non-aseptic process equipment underwent chemical disinfection in a previous step, the post-rinse may occur with clean potable rinse water. The final rinse water is pumped through the CIP circuit to remove residual disinfectant, and is subsequently recovered for use as pre-rinse water. Rinse times and temperatures may vary but are commonly 5–10 min and either cold or warm. To ensure complete removal of chemical solutions, the final rinse is monitored by testing the pH, conductivity or resistivity (compared to the inlet). Water hammer effects, which may occur when the lines are filled at the start of the next cleaning cycle, can be reduced by leaving the post-rinse water in the system. However, when a pipe section between two closed valves is completely filled with a liquid, temperature changes may cause mechanical damage to these valves and seals. Moreover, the continuous presence of post-rinse water in a pipe section may increase the risk of contamination of a food product running in an adjacent process line. This is particularly a risk if both pipes are interconnected and just separated by an ordinary single-seat valve. Single-seat valves may leak and contaminate the food product with post-rinse water if the latter is continuously present against that valve.

#### *Drying*

Following the post-rinse cycle, the process equipment may be purged with heated or ambient temperature sterile air to aid in drying the equipment. The air is commonly blown into the process line through the CIP spray devices or via separate supply ports.

Fully automated control of cleaning programmes is preferable over manual control. Parameters such as rinse, drain and recirculation times, temperatures, detergent concentration and flow rate should all be monitored and governed via either instrumentation or engineering design.

### **10.3.6 Water quality**

Water is the main component in cleaning solutions, usually constituting at least 95%. To obtain optimal and consistent cleaning results, the water used to prepare the cleaning solutions must be of sufficient quality. For CIP

processes, potable water that is fit for human consumption (free from toxic metal ions, spoiling microorganisms and pathogens, etc.) should be used. The following substances or parameters have proven problematic during CIP processes and must be carefully monitored:

- Total hardness: the sum of the carbonate hardness ( $\text{Ca}(\text{HCO}_3)_2$ ,  $\text{CaCO}_3$ ,  $\text{Mg}(\text{HCO}_3)_2$ ,  $\text{MgCO}_3$ ) and the non-carbonate hardness ( $\text{CaCl}_2$ ,  $\text{MgCl}_2$ ,  $\text{CaSO}_4$ ,  $\text{MgSO}_4$ ,  $\text{Ca}_3(\text{PO}_4)_2$ ,  $\text{Mg}_3(\text{PO}_4)_2$ ) can be expressed in mg/l  $\text{CaCO}_3$ . Very hard, hard, moderately hard and soft water have a total hardness of >200 mg/l, 120–200 mg/l, 60–120 mg/l and 0–60 mg/l  $\text{CaCO}_3$  respectively. When the temperature and/or alkalinity of the water increases, the solubility of the constituents that cause hardness decreases, resulting in scale formation. Moreover, excessive amounts of inorganic salts can reduce the effectiveness of the detergents. Total hardness should be <50 mg/l (ideally 5–10 mg/l)  $\text{CaCO}_3$ , and calcium (Ca) and magnesium (Mg) should be present in concentrations of <100 mg/l and <30–50 mg/l (preferably <10 mg/l) respectively.
- Carbonate hardness: carbonates break down when heated, releasing  $\text{CO}_2$  and depositing scale, e.g. on the inside of kettles, evaporators and heat exchangers. These deposits on the equipment surfaces not only reduce the overall heat transfer efficiency of the plant, but can also provide a nucleus for other soil depositions to take place. Alkalinity ( $\text{HCO}_3^-$ ) should be <30 mg/l.
- Conversion of non-carbonate hardness into insoluble deposits: this is due to the presence of certain alkalis. Specific constituents are incorporated into detergents to minimize precipitation.
- Silicates: in high concentrations these may form dull layers on stainless steel surfaces. Concentrations must be <40 mg/l in  $\text{SiO}_2$ , which can be obtained by adding a strong base anion exchanger.
- Iron and manganese: these can make the water more corrosive, cause coloured deposits on equipment surfaces (above 0.3 ppm), and react with sequestrants. Concentrations of Fe and Mn should be <0.2 and <0.05 mg/l respectively. They may be removed by precipitation and filtration.
- Chlorides: these can cause pitting, stress corrosion and failure of stainless steel in amounts as low as 40–50 mg/l and in combination with pH values < 9.5. Municipal water may contain as much as 300–600 mg/l  $\text{Cl}^-$ . Chloride concentrations should be <250 mg/l (preferably <50 mg/l).
- Sulphates: concentrations must be <250 mg/l to avoid corrosion of materials containing iron.
- Nitrates: when converted to nitrite in the gut of babies, these may cause methaemoglobinaemia (blue-baby syndrome). Concentrations over 20 to 50 mg/l will attack iron if the water is soft. In drinking water, nitrate ( $\text{NO}_3^-$ ) concentrations must be <50 mg/l.

- **Turbidity:** caused by suspended solid particles in water. Suspended solids comprise colloidal suspensions (1 to 200µm), clay, fine sand and silt (about 100µm). Suspended solids in a concentration of 1ppm cause visual turbidity, and may form deposits on clean equipment surfaces. With respect to turbidity, drinking water must meet the following criteria: turbidity <1 nephelometric turbidity unit (NTU) (preferably: <0.5 NTU), dry matter (after drying at 180°C) <1000–1500mg/l (preferably: <500mg/l), suspended solids <1mg/l and <25µm, colloidal particles <1mg/l (preferably: none), and silt density index <1. The most appropriate methods to remove suspended matter are sedimentation and filtration.
- **Total bacterial count:** this should ideally be <100 colony forming units (cfu)/ml, with mesophilic and psychrophilic bacteria <5cfu/ml and <50cfu/ml respectively. Coliforms and *Escherichia coli* must be absent in 100ml.
- **Colours, tastes and odours:** these must be absent or organoleptically undetectable. Objectionable tastes, odours and colours may be removed by ozone treatment or activated carbon filtration.
- **Dissolved gases:** O<sub>2</sub>, CO<sub>2</sub> and H<sub>2</sub>S may cause many problems. Dissolved oxygen promotes oxidation of metals, especially iron, brass and galvanized metal. CO<sub>2</sub> may form weak acids that can cause corrosion. Hence, supplementation of additional alkali will be required. H<sub>2</sub>S may disrupt the ion-exchange activity of resins, promote tarnishing of certain metals and cause organoleptic deviations. De-aeration is the most common method to remove dissolved gases.
- **Total dissolved solids (TDS):** the total of all chemicals dissolved in the water is usually not problematic for cleaning and disinfection but should preferably be less than 500mg/l.
- **pH:** should be 6.5–8.5 (max. allowable pH is 10).

If the food manufacturing company is situated in a hard water area, the water is likely to be heavily loaded with minerals that can form scale. Therefore, either the detergent formulation must be adjusted with sequestering agent and additives to keep the calcium suspended or the water must be treated to reduce the mineral content prior to its use for cleaning. It is not recommended to treat the water so that it becomes absolutely soft (total hardness of 0mg/l CaCO<sub>3</sub>) since it can become corrosive. The efficiency of post-cleaning rinses is directly related to water quality. Mineral salts in rinse water are precipitated more readily from alkaline solutions than from acid solutions. Hence the rinse water should be conditioned with acid (pH 6.5 or less) to minimize the deposition of mineral salts onto clean equipment surfaces (Seiberling, 1997).

### 10.3.7 Coverage

All soiled surfaces should be in close contact with the cleaning solution for a sufficiently long time. To achieve this, dead legs in piping should be

eliminated, upwards and downwards pointing dead zones should be avoided, and instrument tees should be as short as possible. The correct tank cleaning devices must be selected (Section 10.7) in order to cover all tank surfaces.

### **10.3.8 Design and construction parameters of the process equipment to clean**

To achieve efficient and effective cleaning, process equipment should be hygienically designed from chemically compatible materials, with minimal electrostatic binding forces and smooth surfaces.

### **10.3.9 Quality of work done by the operators and quality assurance staff**

Some operators put forward higher requirements for quality than others and views on what constitutes cleanliness may differ. When CIP processes are manually controlled by operators, cleaning of a given process equipment can still be run differently, especially if operators do not respect the predefined optimal duration of each step in the cleaning programme. Hence, the predefined level of cleanliness may not be met, despite the use of CIP processes.

The repeatability of a defined cleaning operation is much higher now that most CIP processes are automated, giving more consistent cleaning results. However, humans are still involved for cleaning validation and sampling of the cleaned equipment surfaces to monitor the attained level of cleanliness. Although predefining and monitoring of the level of cleanliness is no longer the work of the operators on the floor, usually the quality control and/or quality assurance staff do undertake this. Even when there is a level of cleanliness predetermined by means of analytical methods that have been proven to generate reproducible and consistent results, if the sampling of the equipment surfaces cleaned or the analysis of the sample are not correctly executed, then the level of cleanliness observed will be null and void.

To reduce the human error factor as far as possible, operators involved in CIP operations should be well trained with basic knowledge about food safety, contamination risks, the differences between manual cleaning and automated cleaning by means of CIP, 'dos and don'ts' of cleaning procedures, monitoring of cleanliness (either visually or by sampling of the cleaned surfaces), what is clean or not clean, safety issues related to manual or automated CIP cleaning, etc.

## **10.4 The main types of CIP systems**

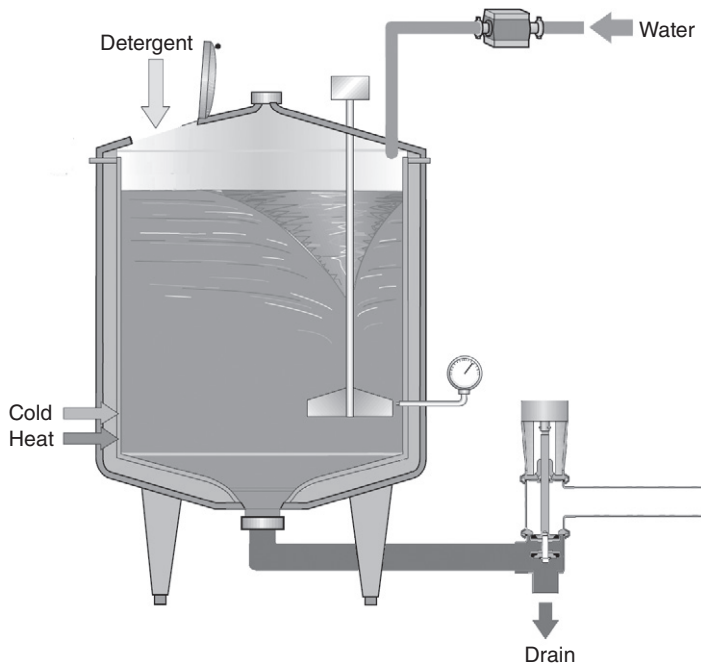
A CIP system is usually composed of one or more tanks, a CIP supply with CIP recirculation pump, metering pumps for feeding cleaning chemicals, a

heat exchanger for heating the cleaning solutions, CIP supply and CIP return piping, valves, instrumentation such as temperature and conductivity probes and pressure transmitters, flow meters and a more or less automated control system.

There are four basic types of CIP concepts: fill-boil-and-dump cleaning, single-path CIP systems, single-use CIP systems and reuse CIP systems. The type of CIP station appropriate for a process plant depends on economic criteria, local regulations regarding water and wastewater, the size and number of objects to be cleaned, the frequency of cleaning operations and the risk of potential cross-contamination by microorganisms and allergens must be considered.

#### 10.4.1 Fill-boil-and-dump cleaning

This method requires that, at the start of a process, there is an ingredient tank with a volume sufficient to contain enough cleaning solution for the whole system to be cleaned. In fill-boil-and-dump cleaning (Fig. 10.4), after manual cleaning, the tank is filled with water and detergent is added. The cleaning solution is then heated to boiling point, and line flushing, which is

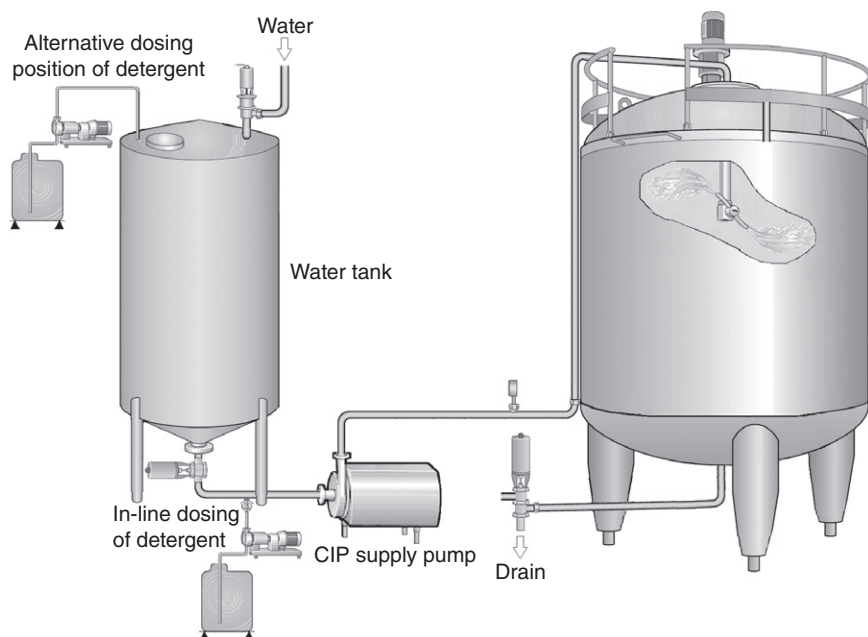


**Fig. 10.4** Fill-boil-and-dump cleaning: after manual cleaning, the tank is filled with water. Detergent is then supplied, and the cleaning solution is heated to boil-up. There is no residual circulation in the cleaning system, and the cleaning solution is drained afterwards.

effective for cleaning piping 75 mm or smaller in diameter, is carried out. This cleaning technique requires no additional piping or spray devices beyond those required for the process itself, so that no or little capital investment is needed. However, in addition to being time and energy intensive, boil-ups do not make the most effective use of aqueous cleaning solutions. There is no residual circulation and the cleaning solution is drained, so the cost of water and detergents used is high. Further the repeatability is poor; the results are often inconsistent or unsatisfactory, which makes this cleaning technique difficult to monitor and validate.

#### 10.4.2 Single-path CIP system

In a single-path CIP system (Fig. 10.5), a freshly made-up cleaning solution is supplied from a single tank filled with water to which cleaning agents are added in the tank or in-line. There is no residual circulation in the cleaning system; wash and rinse solutions are not returned to the CIP installation and the cleaning solution is drained. This prevents soil being spread through other parts of the system. Hardly any investment in additional equipment is needed. The main disadvantage of this system is that cleaning fluids are used only once, meaning that they are discharged at the end of the cycle.



**Fig. 10.5** Single-path CIP system: a freshly made-up cleaning solution is supplied from a single tank filled with water to which cleaning agents are added in the tank or in-line. There is no residual circulation in this cleaning concept; the cleaning solution is drained at the end of the cleaning cycle.

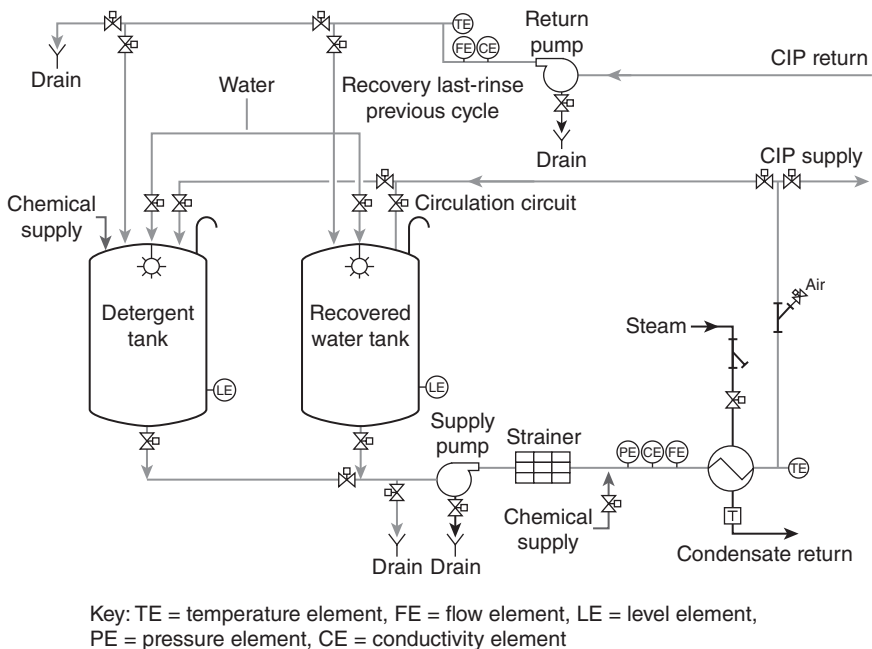


Hence, running costs may be high for detergents, disinfectants, energy and water, and large quantities of effluent are produced, increasing the water treatment and waste disposal costs. Cleaning may also take a long time because, after each cycle, a new batch of cleaning solution must be prepared. The single-path cleaning system is also difficult to monitor and to validate (Majoor, 2003).

This single-path CIP method is only recommended for relatively small process plants, and very dirty or specialized process equipment, for example separation membranes, because of the specificity of cleaning products used. This concept is also appropriate and commonly used when the risk of cross-contamination is high, such as in the pharmaceutical industry (Lorenzen, 2005).

### 10.4.3 Single-use CIP systems

Single-use systems use smaller volumes of solution, automatically adjusted to the required detergent concentration and temperature with a preparation loop. Single-use systems (Fig. 10.6) are usually small packaged units (skids) with one tank, pipes, centrifugal pumps, valves and several dosing pumps



**Fig. 10.6** An example of a single-use system additionally provided with one tank to recover rinse water. The system is heated by direct steam injection, the tank jacket, a heating coil in the tank or an external heat exchanger (courtesy of Sani-Matic, Inc.).

to automatically feed cleaning chemicals from the shipping containers or bulk storage. The cleaning solution can be heated by an external heat exchanger, the tank jacket, the heating coil in the tank or a direct steam injection device. These CIP systems use the solution only once at the lowest possible strength, and discharge it to the sewer at the end of each cycle.

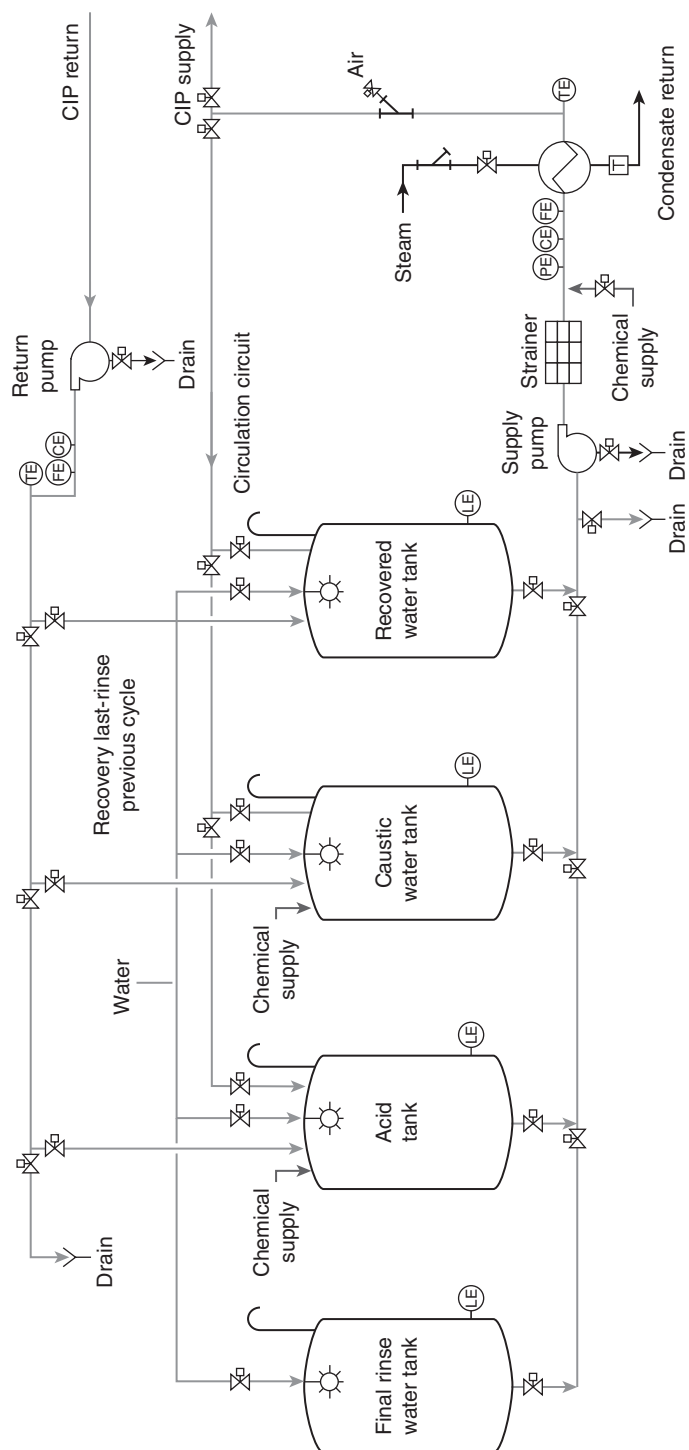
The tank must have a large enough capacity for the process equipment and pipes to be cleaned. In order to reduce losses from intermediate rinsing steps and flush-outs, the inlet and outlet paths for the cleaning media must be kept short, requiring the CIP system to be located adjacent to the equipment to be cleaned and disinfected. As such, consumption of cleaning solutions can be minimized and effluent rates reduced. Sometimes, an additional water tank is installed to retain the last rinse water, which can then be used as pre-rinse in a following cleaning cycle. To further reduce the total amount of water, cleaning agents and energy required for cleaning operations, several installations also have ultrafiltration membranes or evaporators for recovery of water from spent cleaning solutions, which is then temporarily stored as pre-rinse water for the next cleaning cycle.

Single-use CIP systems are small in size, simple in design, low in initial investment, and flexible in application. They are suitable for the cleaning of relatively small but heavily soiled equipment or for processes where cross-contamination is strictly forbidden (process installations with solids and chunks, process equipment containing allergens, membrane plants, etc.). Single-use systems are especially used in the pharmaceutical industry due to the fear of cross-contamination that could arise by recycling cleaning solutions but they are seldom used in the agro-food industry (Rizoulières *et al.*, 2009).

#### **10.4.4 Reuse CIP systems**

*Preparation of cleaning solutions of required strength and at sufficient temperature*

A typical reuse CIP system (Fig. 10.7) consists of a caustic tank, an acid tank, a water recovery tank (e.g. to recover the last-rinse water of a previous cleaning cycle, which is reused as pre-rinse water in the next cycle), and one tank containing the water for the final rinse. All tanks are interconnected by piping, provided with valves and manifold fitted with CIP supply and return pumps. From containers, metering pumps feed exact amounts of concentrated caustic or acid cleaning chemicals directly into the water-filled caustic and acid tanks, or these chemicals are injected in-line into a preparation loop. A preparation loop is a very efficient system, especially when the caustic and acid tanks of the CIP station are tall. For big CIP stations, each tank (caustic, acid and water tanks) is equipped with its own preparation loop. The content of each of the CIP tanks is mixed by recirculation over the corresponding CIP tank through the CIP supply/recirculation pump. Because the conductivity is proportional to the detergent concentration, conductivity sensors can be used to check and



**Fig. 10.7** A typical reuse CIP system consisting of a caustic tank, an acid tank, a water recovery and final rinse water tank, all interconnected by piping, provided with valves and manifold fitted with CIP supply and return pumps (courtesy of Sani-Matic, Inc.).

maintain the strength of the cleaning solutions. Detergent chemicals are generally fed directly on the 'on-demand' basis of a conductivity sensor signal.

The recirculation loop is also fitted with a plate or tube heat exchanger to heat the solutions to and maintain them at the desired temperature. Alternatively, in-tank heating via a jacket or heating coil, or direct steam injection in the tank or preparation loop may be applied. If an external heat exchanger is used, the steam supply to this is controlled by the temperature signal of the temperature sensor positioned in the recirculation loop over the appropriate acid or caustic CIP detergent tank. Recirculation goes on until the cleaning solution is at the adequate chemical strength and temperature to start the CIP process.

#### *CIP supply*

When the solution is ready, the CIP tank recirculation valve closes and the CIP supply valve opens, allowing the cleaning solution to flow into the CIP supply line. The CIP supply line is connected to the piping that needs to be cleaned and to the spray devices located in a vessel or other pieces of process equipment. Dry running of the supply pump could damage the pump and is prohibited by a no-flow sensor.

#### *CIP return*

The cleaning solutions can be routed back to the CIP system either using gravity, if feasible, or a low-speed CIP return pump. The return pump should be prevented from dry running with a no-flow sensor, to avoid premature failure of the pump. Sometimes, the return pump is aided by an eductor. An eductor generates suction in the return line, so that the return pump never air-locks. To generate the suction, the eductor requires a motive fluid that can be delivered by a small motive pump. One of the CIP solutions (usually the same one as the returning solution) is sent from the source tank through the eductor and back to the source tank. Thus the motive fluid is different at different stages of CIP. The CIP return line may have a sample point in order that the cleaning process can be validated (Seiberling, 1997; Christi, 1999).

#### *Phase separation and recovery*

Upon return to the CIP system, the solution can be kept in one of the CIP tanks or be diverted to drain. Reuse CIP systems are generally programmed to 'waste' a small part of the solution at the end of each cleaning cycle in order to continuously remove soiled solution from the system. Fresh water is then added to bring the solution tank to the normal operating level, after which the conductivity cell-based chemical feed system will add more chemical. If the process equipment goes through a caustic cleaning step, the detergent solution is not polluted as quickly and can be reused many times. This is especially possible in process plants where parts of the process

equipment are not heavily soiled, and where the pre-rinse water removes a high percentage of soil during the preliminary rinse.

Caustic and/or acid detergent solutions can only be recovered in large amounts if the cleaning solution phases and rinse waters are adequately separated. Separation and recycling of solutions is governed by a conductivity sensor that is installed at the end of each CIP return line on the CIP station. When this sensor detects that the conductivity of a solution is higher than a predetermined target value, the CIP solution is returned to the corresponding detergent tank. The cleaning solution is flushed away by the water in the next rinse, so that the conductivity signal decreases and drops below a pre-set value. In turn this triggers a change-over valve to route the rinse water to drain instead of going to the detergent tank. Once a predetermined minimum conductivity value has been reached, indicating complete removal of acid or caustic from the system, the intermediate or final rinse is stopped. Usually the entire CIP sequence is automated, allowing the CIP system to stop regularly at specific steps.

Separation of solutions is only efficient if there is minimal intermixing between cleaning solutions and water phases. Hence, the transition and boundary between two successive phases (e.g. between the caustic and rinsing sequence) must be sharp. The transition between the two phases will be long if there is too much intermixing due to poor hygienic design of the process equipment (e.g. dead legs) or because different equipment units are cleaned in series. Separation of solutions could be controlled using timers but this is not as effective as separation by means of conductivity sensors.

#### *Additional tanks*

The water consumption in a reuse system can be further optimized by providing a recirculation facility for the hot water. Moreover, the unit could be fitted with neutralization tanks to neutralize the alkali and/or acid solutions before disposing of them into the effluent system. The capacity of the tanks will be decided by the circuit volume, temperature requirements and desired cleaning result. An ideal reuse CIP system would have the ability to fill, empty, recirculate, heat and dispense contents automatically.

#### *CIP reuse systems compared with single-use CIP systems*

Reuse systems are more complex than single-use systems, making the additional investment costs higher. However, the payback period is short because of the savings in water, detergent chemicals and energy used.

## **10.5 Centralized/decentralized CIP systems**

The size of the process plant and other criteria such as cost effectiveness and food safety determine which of three types of CIP systems can be used (Bylund, 1995; Majoor, 2003).

### 10.5.1 Centralized CIP station

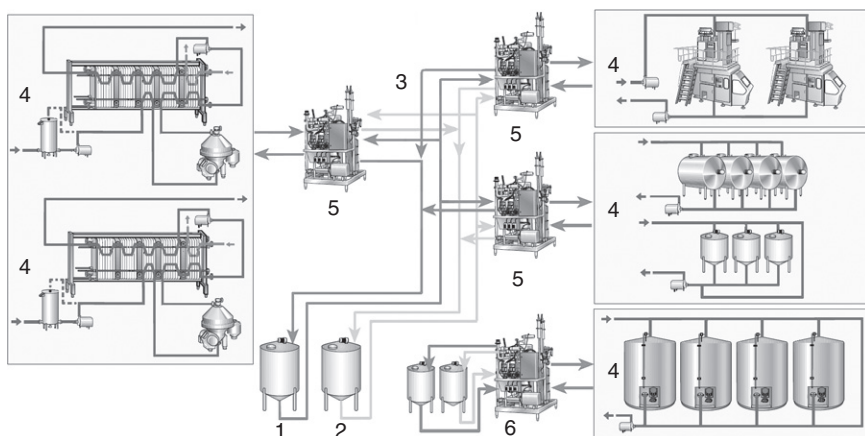
A centralized CIP system is normally used in small plants where the distance between the CIP station and the equipment to clean is relatively short. In the 1980s, it was quite common to build large CIP systems for cleaning an entire production plant. However, incidents with finished products that were found to be contaminated with *Salmonella* and *Listeria* caused food manufacturers to cease cleaning all process lines in different areas (a mixture of low- and high-hygiene risk areas) of the food factory with the same CIP station. It proved better to separate at least the cleaning of the 'raw' and the 'processed' side of the plant as mixing these increased the risk of re-contamination of any finished food that underwent a further decontamination step. This was achieved by using a centralized CIP unit with corresponding satellite CIP stations or a system of de-centralized CIP stations. The major drawback of centralized CIP stations is the expense. Cleaning solutions and rinsing waters must be transported over long distances, so heat losses are more probable and larger volumes of water and detergent chemicals are required. An advantage is that only one programmable logic controller (PLC) is required, which controls the in-place cleaning of all equipment in the food factory. Detergent chemicals and detergent solutions are only stored or prepared at one location, which is beneficial for the safety of the operator, because less space is required and because no additional tanks, pumps, valves, etc., are located in other process areas where they may compromise the hygiene in the process room.

### 10.5.2 Centralized CIP unit with several satellite CIP stations

In this system, the alkaline and acid detergent solutions are still stored in a main station, which distributes these cleaning solutions to individual satellite CIP units (Fig. 10.8). The supply and heating of the rinse waters, however, are arranged locally at the satellite stations. These stations operate on the principle that the various stages of the cleaning programme are carried out with a carefully measured minimum volume of liquid, just enough to fill the circuit to be cleaned. A powerful circulation pump forces the detergent solution through the circuit at a high flow rate. Unlike the more common practice of detergent recycling used in centralized systems, smaller CIP satellite stations, which use the cleaning solutions in smaller volumes, only do so once. This 'once through' usage works on the basis that the composition of the detergent solution can be optimized for a certain circuit. This solution is then considered 'spent' after one use although, in some cases, it may be used for pre-rinsing in a subsequent cycle.

### 10.5.3 Completely decentralized system of smaller CIP stations

In this concept the main station is replaced by a number of small CIP stations, each of which cleans specific process equipment or groups of



**Fig. 10.8** A centralized CIP unit with several satellite CIP stations and one completely decentralized CIP station: 1 alkaline storage tank, 2 acid storage tank, 3 CIP supply and return pipelines, 4 equipment to be cleaned, 5 satellite CIP units, 6 decentralized CIP system with its own detergent tanks (Bylund, 1995).

process equipment in a given sector of the food factory. For that purpose, each separate CIP station is located adjacent to the relevant process line(s). Decentralized CIP stations (Fig. 10.8) are recommended for large process plants where the distance between a centrally located CIP station and peripheral CIP circuits would become extremely large. This concept allows solutions and rinsing water to be transported over much smaller piping trajectories, reducing heat losses and the volume of water needed to fill the whole piping system. Because less water is involved in the rinsing process, residues from the first rinse are obtained in a more concentrated form, reducing the wastewater load that the treatment plant has to handle. Further, less heat is lost during the CIP operations, therefore greatly reducing steam consumption. This system also has the same benefits as the satellite CIP stations mentioned above. However, major drawbacks of decentralized CIP units are that they require the detergent tanks to be in the production area and they need one PLC at each CIP station.

## 10.6 Design of CIP line circuit

### 10.6.1 Obstructive objects in the flow

Obstructions in the flow are sometimes unavoidable; for example pH probes, conductivity sensors and temperature sensors. The positioning of these items in relation to the flow direction, during both processing and cleaning, should exclude 'shadow' areas which cleaning fluids would miss. For this reason the flow should go in the same direction during cleaning and processing.

### 10.6.2 Exclusion of 'dead areas'

A 'dead area' is one where either product or cleaning fluid can collect. The design of the CIP infrastructure must be free of these 'dead areas', otherwise cleaning fluid will not be able to contact the internal surfaces of a pocket or leg at the required velocity. The upward-pointing T-pieces in pipes for the installation of instrumentation are a good example of this problem. Cleaning fluid either bypasses these areas altogether or fails to circulate with sufficient velocity to remove soil effectively.

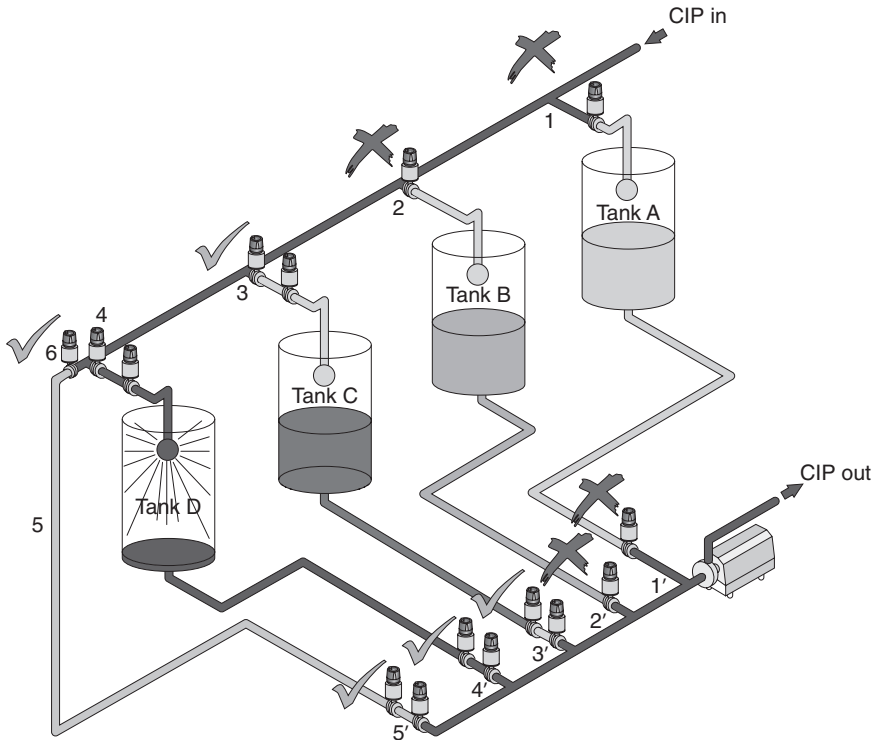
To avoid 'dead areas', valves should be installed very close to the main CIP supply line at the upstream side of the branches to the process tanks, as shown in Fig. 10.9. If these valves are instead located at the downstream side of these branches, too far from the CIP supply line, dead areas of stagnant cleaning solutions will collect. Similarly, if the valves on the branches from the process tanks to the CIP return line are not positioned close to that return line, stagnant liquid, consisting of pre-rinse water and product residues, or cleaning solutions, will accumulate in the return branches. Valves should be installed very close to the main CIP return line and/or non-return valves installed in the CIP return branches to avoid 'dead areas'. Non-return valves could, however, obstruct the CIP return flow. Various types of valves are available that can branch pipelines without creating stagnant areas (for example, flow-through or cross-flow valves).

The CIP supply and CIP return line should be directly interconnected beyond the branches to or from the process tanks, as shown in Fig. 10.9. This loop must still be provided with a block valve. Cleaning solutions and rinsing waters can be removed over the whole CIP supply and CIP return circuit by opening the block valve. As circulation can then occur over the entire CIP supply–CIP return circuit, the CIP lines will no longer remain polluted by residues, such as those from the former pre-rinse or pre-wash. Moreover, less intermixing between successive liquid phases of a cleaning cycle will occur, resulting in less wastage of detergent chemicals.

### 10.6.3 Self-drainability of the CIP supply and CIP return lines

It is a general rule in the food industry that products should be transported through process piping that is free of dead ends, properly supported to prevent line sagging and provided with a downward slope of 1 m per 120 m in the direction of flow, in order to avoid standing 'pools' of liquid food product forming. Product, cleaning solutions and rinse waters must all be quickly removed. Self-draining piping systems facilitate evacuation of residual rinsing water during and/or after cleaning, which results in less intermixing of the rinse waters with the cleaning solutions. A better separation of successive liquid phases of a cleaning cycle (e.g. separation of rinse water and cleaning solution) leads to less wastage of detergent chemicals along with the rinse waters when drained. The concentration of detergent chemicals in the cleaning solutions is also better preserved.





**Fig. 10.9** To avoid 'dead areas', valves should be installed very close to the main CIP supply line at the upstream side of the branches to the tanks (branches 2, 3 and 4). During in-place cleaning of, for example, tank D, there will be a dead area in branch 1 to tank A. That stagnant cleaning liquid will not be properly removed when changing to the next stage of the cleaning cycle of tank D. The branches from the process tanks to the CIP return line should also have valves positioned close to the CIP return line (branches 2', 3', 4' and 5'). Again, in branch 1' to the CIP return line, there is a dead area. Further, the CIP supply and CIP return line should be directly interconnected (5) beyond the branches to or from the process tanks. This loop (5), which is provided with a block valve (6), allows removal of cleaning solutions and rinsing waters over the whole CIP supply and CIP return circuit. A fluid from a previous step in the cleaning cycle can be replaced by a subsequent one via the interconnected CIP supply-CIP return line. Only one single-seated valve is installed in branches 1 and 2 so the product in tanks A and B is at risk of contamination if cleaning fluids leak over the valve seats. Contamination of food product may also occur if cleaning fluids leak over the valve seats of the single-seated valves in branches 1' and 2'. The CIP fluids can be kept separate from the product by using a double block-and-bleed arrangement of two butterfly valves in series with an inline separation cavity between both butterfly valves (points 3, 4, 3' and 4').

Therefore, all pipe runs of the CIP system (CIP supply and CIP return piping) should be equally supported and sloped downwards to the same extent as the process piping. CIP supply and return lines are usually drained when a cleaning procedure is terminated, and should therefore have drain valves at appropriate places.

#### **10.6.4 Separation between product and CIP solutions**

To avoid contamination of the final product with cleaning fluids, process circuits that are cleaned in-place must always be properly separated from the food product. Single-seated valves between cleaning fluids and food product may leak over the valve seat, which, moreover, cannot be observed from the outside. The systems detailed below aim to eliminate these risks.

##### *Key pieces*

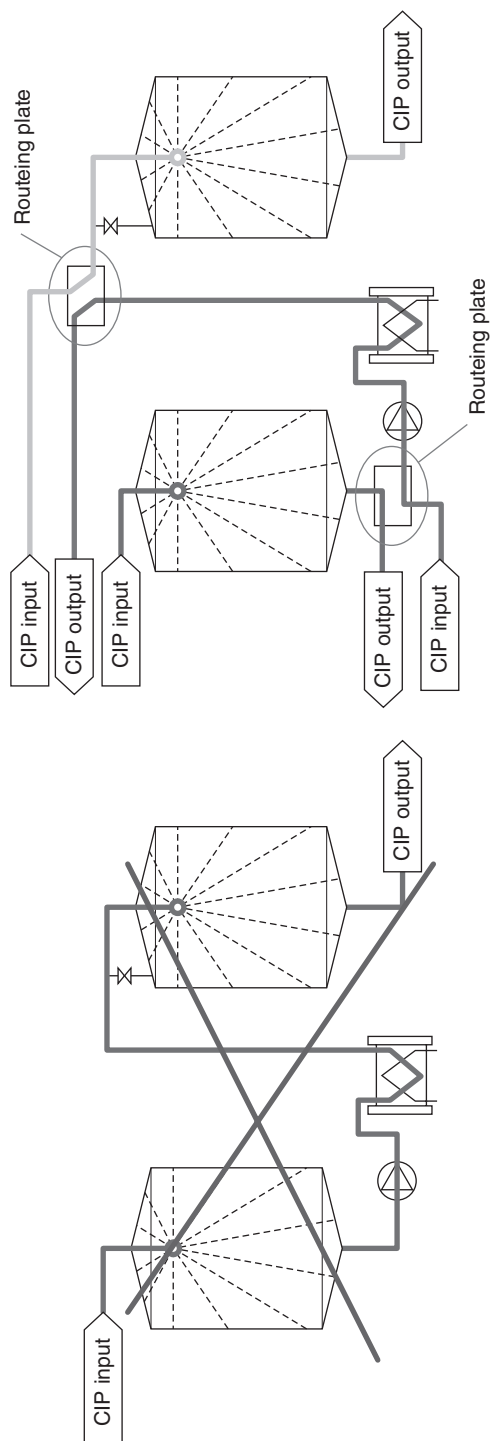
The use of key pieces offers a high degree of security. If installed at two places in a tank installation, the first will be positioned at the bottom when the product is being handled, while the second will be positioned at the top (i.e. above spray ball(s)) during the CIP operation.

##### *Transfer panels*

Transfer panels (Fig. 10.10) are composed of a series of 'plug-in' ports (with tri-clamp ends) welded into a 316L stainless steel plate. Transfer panels can be free standing with legs and foot plates or integrated into the wall. The nozzles are connected by hard sanitary stainless tubing to the inlets and outlets of process vessels or other functional parts (such as the CIP system) in an all-welded construction. The ports are connected with sanitary U- and J-bends. Proximity switches enable electronic confirmation that the lines are properly connected before a particular process circuit can be initiated, thus preventing accidental mis-transfers. A system of transfer panels is suitable for small plant operations, and allows separate in-place cleaning of different process units.

##### *Double block-and-bleed butterfly valve system*

A double block-and-bleed arrangement of two butterfly valves in series with an inline separation cavity between both butterfly valves can be used to safely separate CIP fluids from product (which can be observed in Fig. 10.9). Double block-and-bleed systems consisting of two sets of butterfly valve components arranged in series within a single integral valve body can now provide an inline separation cavity when both valves are in the closed position. That cavity allows safe in-line separation of CIP fluids and product. Facilities are provided to drain leaking fluids from the system, should either of the separate valve seats fail. This system also allows washing of the separation cavity (Fig. 10.11).



**Fig. 10.10** Two flow plates can be used to ensure the two process units can be cleaned separately via two different CIP circuits.



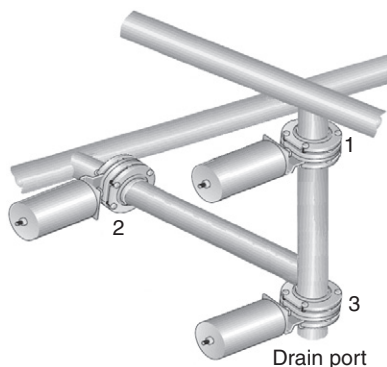
**Fig. 10.11** A double block-and-bleed arrangement of two sets of butterfly valve components arranged in series within a single integral valve body which can be used to safely separate CIP fluids from food product. The separation cavity can be flushed with CIP liquid and subsequently drained. Their position also facilitates a drain into the atmosphere should either of the separate valve seats fail (courtesy of Pentair Südmob).

*Mixproof system of three single-seated shut-off valves*

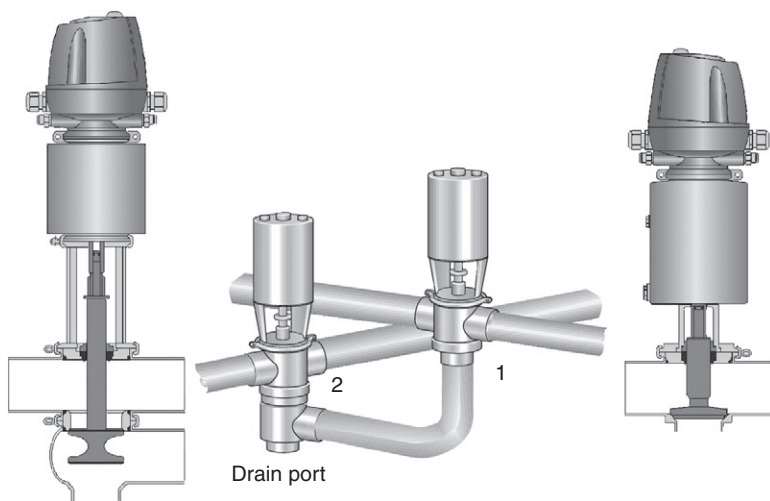
The mixproof system shown in Fig. 10.12 allows product to flow from one line into the other. When properly closed off, two different media can flow through the two lines without being mixed by employing a suitable combination of single-seated shut-off valves. Any leakage is immediately observed and can be drained without any possibility of one medium being mixed with the other (Bylund, 1995).

*Mixproof system of one shut-off valve and one change-over valve*

A mixproof system with one shut-off valve and one change-over valve (Fig. 10.13) allows the product to flow from one line into the other. When both valves are closed, the lines are isolated from each other and two different media can flow through the two lines without being mixed. Should either of the separate valve seats fail, leakage may be observed and drain without any possibility of one medium being mixed with the other (Bylund, 1995).



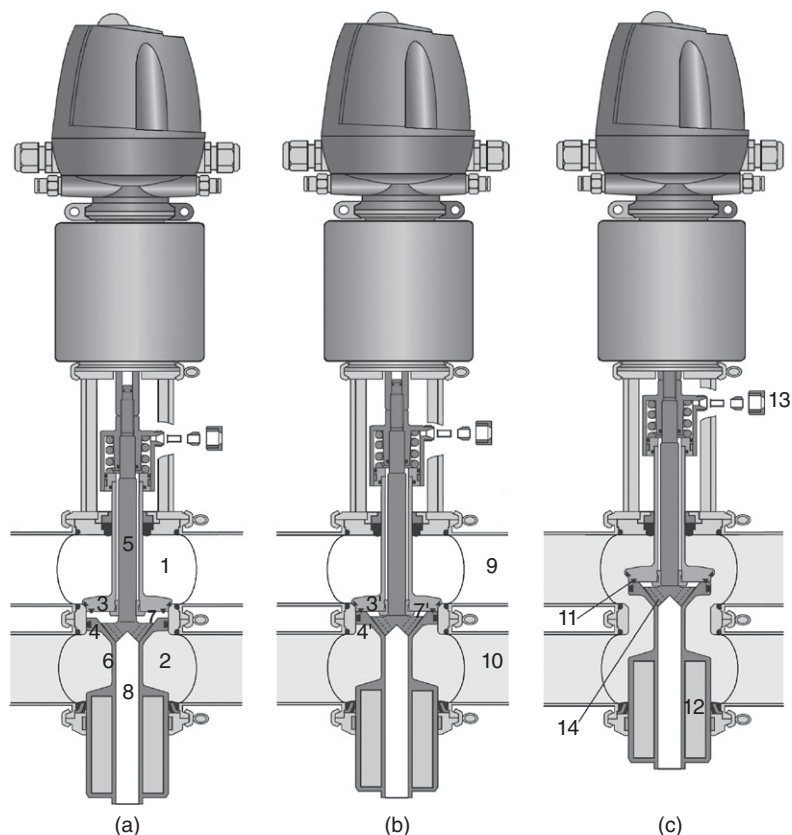
**Fig. 10.12** Mixproof intersections can be designed by a suitable combination of three single-seated shut-off valves, to allow safe in-line separation of CIP fluids and product. When valves 1 and 2 are shut off, the line intersection between both valves can be opened to the outside of the system by opening valve 3.



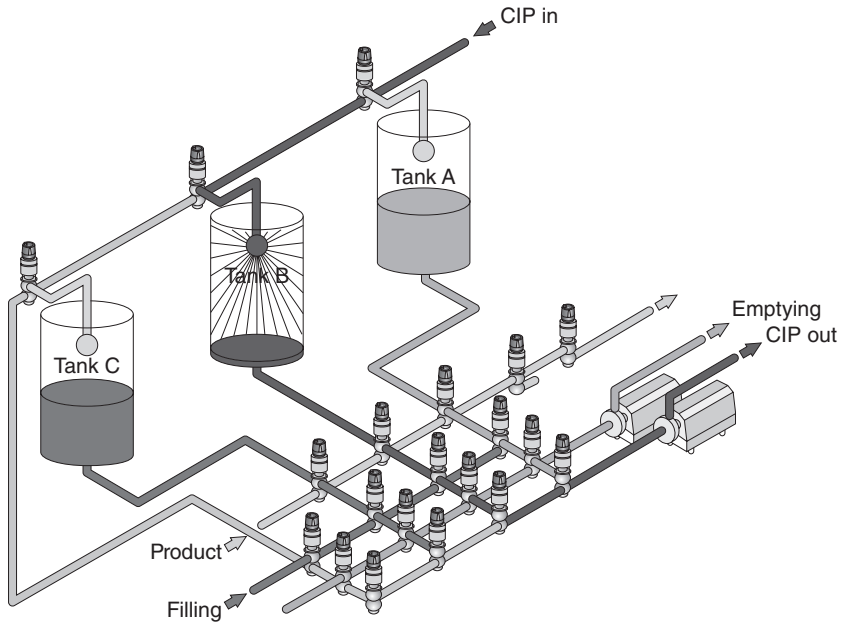
**Fig. 10.13** Example of a mixproof system with one shut-off valve (1) and one change-over valve (2). When both valves are closed (as demonstrated), the line intersection between both valves is open to the surroundings, and any CIP solutions or product will leak out of the system via the drain port (courtesy of GEA Tuchenhausen GmbH).

#### *Double-seated mixproof valves*

Double-seated mixproof shut-off valves (Figs 10.14 and 10.15) are used for the separation of incompatible media such as cleaning solutions and liquid food product. In the closed position of the valve (non-actuated position), there are always two seals between the pipes. If one of the seals fails,



**Fig. 10.14** (a) A double-seated mixproof valve consisting of a valve housing with: an upper (1) and lower (2) valve chamber, an upper (3) and lower (4) valve disc (connected to the upper (5) and lower (6) valve shaft respectively), and a separation cavity (7) acting as a leakage chamber, open to detect leaks and drain them via a drain pipe (8) in the lower valve shaft. The valves operate independently of each other. (b) To open the connection between the upper (9) and lower pipeline (10), the actuated lower valve disc (4') is raised off its seat first and then moves upwards a short distance before contacting the upper valve head (3'). This gradually decreases the drainage chamber (7') between the upper and lower body. (c) Both valve discs then move closer together into the open position. Meanwhile, in more modern double-seated mixproof valves, the remaining cavity between the upper and lower valve discs remains sealed against the product area (11). It is important that the lower plug is hydraulically balanced (12, balancer) to prevent pressure shocks from opening the valve and allowing products to mix. When the valve closes, the upper plug seals first and then the lower plug. Both opening and closing of double-seated mixproof valves may allow very small product losses when entering the cavity between the two valve discs during operation. However, this cavity can be flushed clean with cleaning fluid via a hose connection (13). The cleaning fluid will drain to the outside via the bores (14) and drain pipe (8) of the lower closure device. In aseptic applications, steam or a sterile barrier may be applied in the opening vent to prevent microorganisms from entering (courtesy of GEA Tuchenhausen GmbH).

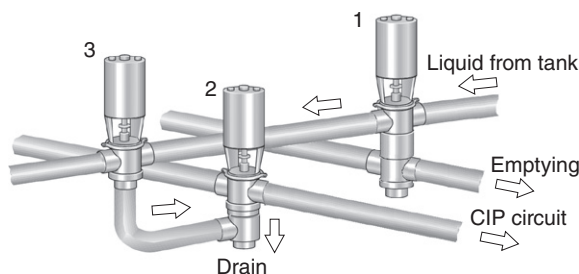


**Fig. 10.15** Example of a double-seated mixproof shut-off valve system (courtesy of GEA Tuchenhausen GmbH).

leakage may drain, via the outlet, out of the system without mixing with the product in the second pipe.

Double-seated mixproof valves also need cleaning; both the upper and lower chamber of the valve housing are soiled by the product as it goes through the pipeline; the seat area between the two chambers is soiled when the valve is in the 'open' position; the cavity with the drain pipe in the bottom shaft requires cleaning because of operational leakage and leakage due to worn seat seals. The housing chambers can be cleaned in-place independently of each other, with the shaft seal on the one side and the seat seal on the other. The seat seal and leakage chamber can be cleaned by seat lifting, periodically during each cleaning phase. The duration of the lifting pulses themselves and the intervals between them depend on the level of soiling but are generally between 10 and 60 seconds, with 3–5 minutes between pulses. As an alternative to cleaning by seat lifting, cavity spray cleaning via an external CIP line connected to the leakage chamber can be done. Shaft cleaning is undertaken to reach the shaft surface and the area behind the shaft seals (Lorenzen, 2005).

Figure 10.15 shows a system with double-seated mixproof valves at critical points. Because of the high costs of such valves, they can be replaced at the points of connection to the CIP circuit by mixproof systems with one shut-off valve and one change-over (flow-diversion) valve as shown in Figs 10.13 and 10.16. An additional advantage is that a process tank can be



**Fig. 10.16** Because of the expense of mixproof valves (1), they can be replaced at the points of connection to the CIP circuit with a mixproof system with one change-over (flow-diversion) valve (2) and one shut-off valve (3).

drained independently of the CIP circuit. These same safety precautions have to be taken when formerly cleaned and rinsed parts of a line are connected with parts that will be cleaned later by other CIP supply circuits. It is important to prevent cleaning liquids from penetrating unnoticed into already clean parts of the system.

## 10.7 Cleaning of process vessels, large-volume equipment and tanks

### 10.7.1 Major objectives of spraying or jetting the vessel, equipment or tank surfaces with cleaning solution

As an alternative to manual or fill-boil-and-dump cleaning (see Section 10.4.1), the interior of tanks, vessels and other large-volume pieces of equipment is best cleaned with stationary or rotary tank cleaning devices. Compared with manual and fill-boil-and-dump cleaning, they permit fast, productive, consistent and reproducible high-quality cleaning. They also ensure operator safety, less cross-contamination between product batches, fewer out-of-specification products, lower running cost (due to reduced consumption of water, cleaning agents and energy during CIP), less effluent and reduced downtime (and therefore increased productivity). However, some tank cleaning technologies can reduce costs more than others.

### 10.7.2 Key parameters that determine the effectiveness of a tank cleaning process

Tank cleaning is defined by Sinner (1960) as spraying or jetting of vessels, equipment or tank walls with a hot cleaning solution, to loosen and remove the soil using the impact of the spray or jet streams and/or by the mechanical action of the free-falling film of cleaning solution along the vessel surface. Tank cleaning devices use chemical (detergent chemicals), thermal (heat) and mechanical/kinetic energy to clean the surfaces; three of the four factors



in what has become known as ‘Sinner’s circle’ that allow the cleaning process to take place. The importance of each of these factors is different for each of the three broad categories of tank cleaning devices, which include:

- stationary spray devices;
- rotary spray devices;
- rotary jet devices.

### **10.7.3 The role of tank cleaning devices in the energy and cost efficiency of a tank cleaning process**

Increasing the mechanical action factor in a tank cleaning process allows for significant reduction of the higher cost factors in the Sinner’s circle, including heat, detergent chemicals, time and water. Savings on energy used in the recirculation and heating of cleaning solutions, and on water usage provide significant financial benefits to the food manufacturer. Moreover, the cost of energy and water is still rising, and likely to continue to rise. The time spent for cleaning reduces the time for the production of food products. Therefore, reducing the cleaning cycle time always has a direct financial benefit.

### **10.7.4 Effect of mass concentration and velocity on the impact per unit tank area of a fluid stream expelled from a cleaning nozzle**

The resultant force of a fluid stream acting on a surface is equal to the rate of change of momentum (Moerman and Leroy, 2002):

$$F = \frac{\Delta(m.v)}{\Delta t} = \frac{v.\Delta m}{\Delta t} + \frac{m.\Delta v}{\Delta t}$$

This equation shows that the impact force of fluid hitting an area of the target surface changes with either the velocity or the mass. As the distance from the tank cleaning device increases, the water spray or jet breaks up due to collapse of unstable fluid sheets by internal friction or due to the shearing action and entrainment of air. When drops and droplets become smaller, their mass decreases concomitantly such that they hit the target surface (e.g. tank wall) with much less force. Moreover, moving drops are decelerated by air friction, with smaller drops losing velocity more rapidly than larger ones. Hence, the smaller sized droplets with lower velocity will hit the target surface (e.g. tank wall) with much less force.

The highest impact per cm<sup>2</sup> in a specific target spot will be obtained if the fluid mass remains concentrated along the centre line over the longest possible stand-off distance  $L$  from the nozzle. Further, the high-density water jet or spray will better maintain its velocity as it moves towards the tank wall. However, if the same water mass is distributed over a larger area,

it will have much less impact per  $\text{cm}^2$  at that specific target spot, especially because the drops and droplets will also lose a lot of their initial velocity.

The type of nozzle, spray angle, spray pattern, spraying pressure and rotation speed (rotary spray and jet device) determine the spray/jet concentration, distribution, velocity and impact. Other factors also influence the spray/jet concentration, such as the viscosity and surface tension of the cleaning solution and the specific gravity which affects both mass and velocity depending on the direction of the spray and jet.

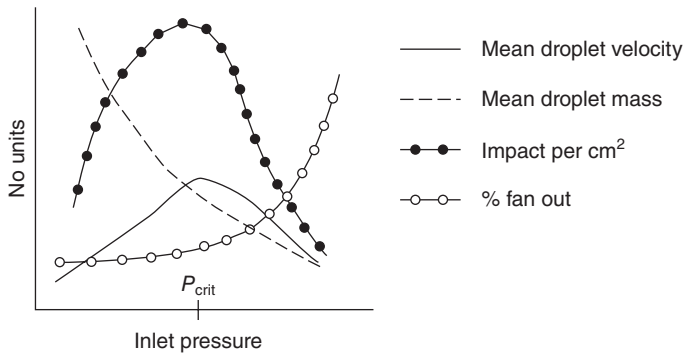
Every factor that promotes the break-up of the water sprays or jets will decrease the impact of the cleaning fluid on the tank wall. One of these factors is fluid pressure. Although it is widely thought that increasing the nozzle's inlet pressure is beneficial for better cleaning, there is a certain pressure limit beyond which stationary spray devices become prone to atomization. Instead of a spray of cleaning solution hitting the vessel wall surface, a fine, atomized cloud of drops will drift into the air and all impingement action will be lost (Fig. 10.17). The throw length of the water sprayed will decrease drastically, because, if dispersed, the sprayed water can no longer wet the vessel wall at a considerable distance from the nozzle.

Also, with free-spinning rotary spray devices, increasing the pressure beyond a certain critical pressure limit  $P_{\text{crit}}$  will cause a rapid decrease of their cleaning power (Fig. 10.17). When they rotate at too high a speed, the compact solid fluid streams produced by these spray devices break open very quickly, such that they have less impact. However, free-spinning rotary spray devices still remain effective for wetting and provide complete coverage because water is distributed to the entire tank almost at the same time.

To avoid a decrease in impact of the water expelled from the cleaning device with increasing inlet pressure, tank cleaning equipment manufacturers have developed rotational controlled (also called constant speed) rotary spray devices with a built-in speed reduction mechanism. This suppresses the rate of rotation of the rotary spray component when the pressure exceeds a critical pressure limit  $P_{\text{crit}}$ . An increase of the inlet pressure of a rotational controlled tank cleaning device does not result in dispersion or atomization of liquid but in more impact of the water sprays on the surface. However, a speed-controlled cleaning device only distributes liquid to a limited area of the tank at once.

### 10.7.5 Selecting the most appropriate tank cleaning devices

It is very difficult to compare the performance and effectiveness of the multitude of cleaning devices available worldwide, because test operating conditions are often so different. Experience has also shown that a universal solution does not exist, because the problems (e.g. soil type) and challenges the food manufacturer has to cope with vary case by case. Table 10.3 gives



**Fig. 10.17** By forcing liquid through a nozzle or orifice, pressure is converted to velocity energy. But as distance from the cleaning nozzle increases, the water spray or jet starts to fan out and gradually breaks up into smaller drops and droplets with decreased mass and velocity, resulting in a decline in their impact per  $cm^2$ . Beyond a critical pressure, that process of breaking-up is accelerated due to atomization, resulting in a significant drop in the impact per  $cm^2$ . But the same graphic may also explain why, beyond a critical pressure limit, the cleaning power of free spinning rotary spray devices starts to decrease with increasing pressure. When they rotate at too high a speed, the compact solid fluid streams produced by these spray devices break open very quickly, and therefore become less effective (Moerman and Leroy, 2002).

an overview of several factors that the food producer must consider when choosing the right cleaning device for their cleaning process. This requires comparable information that can only be obtained by performing controlled tests under the same conditions of soil type, cleaning solution, liquid temperature, cleaning devices pressure, flow rate, cleaning time, etc., for each cleaning device that the food manufacturer uses. Experiments performed by several research groups revealed that no specific cleaning device is preminent for all applications, because each has its own advantages and disadvantages (Welander, 2002).

## 10.8 Spray and jet devices for CIP

### 10.8.1 Stationary spray devices

Stationary cleaning devices (Fig. 10.18) are static spray devices that spray the cleaning solution in a static pattern onto the interior surfaces of a vessel, equipment or tank (often the upper region of the tank). The cleaning result relies more heavily on chemical action, the effect of temperature and the duration of the cleaning process than on mechanical action. The mechanical action to loosen and dissolve the residues is provided by the gravity-assisted dispersion (wetting) and cascading of the cleaning media on the lower parts of the vessel, equipment or tank. The theoretical turbulence of the

**Table 10.3** Several issues that have to be considered in the selection of the most appropriate tank cleaning device for the cleaning of a given process vessel or tank (Moerman and Leroy, 2002)

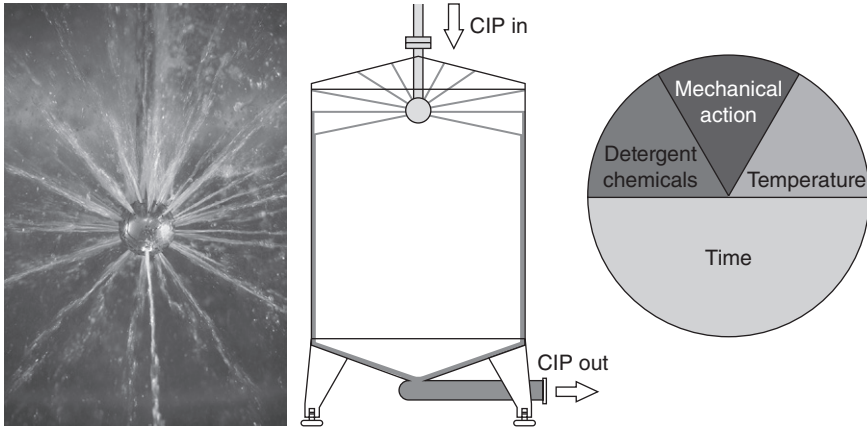
- 
- Soil type (determining the cleaning impact required)
  - Application conditions
    - chemical, corrosive and explosive environments
    - temperature during production and washing conditions
  - Tank dimensions (longest distance between the tank cleaning device and the furthest point in the tank)
  - Tank shape and position
  - Internal tank structure (coils, baffle plates, agitators, flange and port connections)
  - Hygienic design of the equipment to clean
  - Positioning possibilities of the tank cleaning machine
  - Corrosivity of the cleaning solution
  - Temperature of the cleaning solution
  - Available cleaning time
  - Spraying pressure required versus available pump pressure
  - Water consumption in view
  - Self-cleaning power of the tank cleaning nozzle (especially important for permanent installation)
  - Robustness and wear
  - Ease of application and maintenance
  - Energy consumption
  - Bacteria tightness
  - Documentation (Food and Drug Administration (FDA), European Hygienic Engineering and Design Group (EHEDG), material certification, etc.)
  - Pay-back time
- 

free-falling film is only slightly above the laminar flow ( $1000 < Re < 2000$ ), and the wall shear stress  $\tau_w$  is of the order 2–3 Pa at 60 °C. Some pre-defined areas may require more mechanical cleaning. Most stationary tank cleaning devices provide this but the rest of the tank will still only be cleaned at low shear stress where a soaking action is taking place (Alfa Laval Tank Equipment A/S, 2004; Jensen *et al.*, 2011).

The best well-known tank cleaning devices in this category are now described.

#### *Static spray balls*

Static spray balls (Fig. 10.18) are spherical thin-walled (1 mm) or thick-walled (2–6 mm) non-rotating spray devices available in various materials, covered with bore holes that produce many small semi-solid stream sprays. Spray balls are the most widely applied vessel cleaning devices. Yet they themselves have nearly zero cleaning power and only provide partial direct coverage of the tank surface with fluid. Direct wetting is frequently limited to the head of tank, while indirect wetting of the other parts of the tank is due to the cascading flow of liquid running down the tank walls. They can



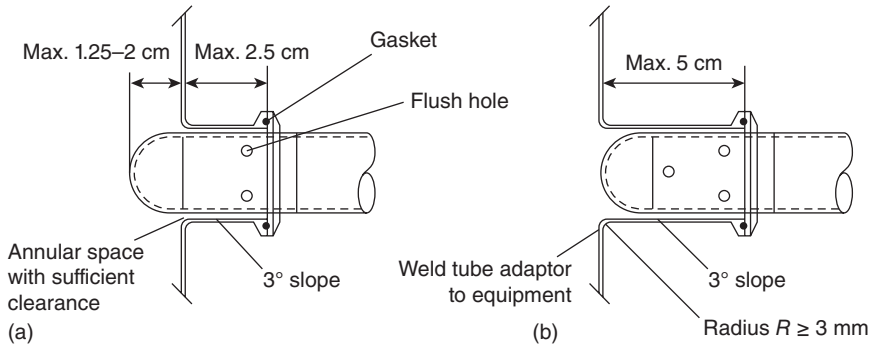
**Fig. 10.18** Stationary cleaning devices spray the cleaning solution onto the interior surfaces of the vessel, equipment or tank. Spray balls with a 185–195° upward spray pattern onto the upper region of the tank are recommended for a cleaning result that relies more heavily on chemical action, temperature and duration of the cleaning process than on mechanical action. The mechanical action to loosen and dissolve the residues is provided by the gravity-assisted cascading of the cleaning media on the surface of the vessel, equipment or tank (courtesy of Alfa Laval Tank Equipment A/S).

be installed in any position and produce a 360°, 270° (upward or downward), 180° (upward or downward) or 90° (upward) spray pattern. This is just enough to exert a rinsing effect sufficient to remove soluble non-sticking residues from the interior surfaces of small vessels with a maximum diameter of 4–6 m, or from tanks without internal structures such as agitators, baffle plates, dip tubes or heating devices. In order to clean tanks with a larger diameter, higher flow rates are needed to ensure the turbulent free falling film covers the tank wall. At these rates, the velocity with which the liquid is expelled through the holes of the static spray balls leads to jet or spray dispersion. However, dispersion may be suppressed by using thick-walled static spray balls where each hole drilled through the thick wall is virtually a nozzle tube, so that the fluid streams travel much farther than normal before breaking up.

One disadvantage is that spray balls can act as a strainer and trap debris. Therefore, pre-filtration of recycled cleaning solutions is required. Holes must also be regularly inspected for blockage, and a drain hole should be provided for self-drainage.

#### *Bubble spray and bent tube spray devices*

‘Bubble spray’ devices (Fig. 10.19) are hollow hemispheres with small holes that allow cleaning solution to pass through them under pressure. The cleaning solution, delivered via the supply tube, is distributed in precise



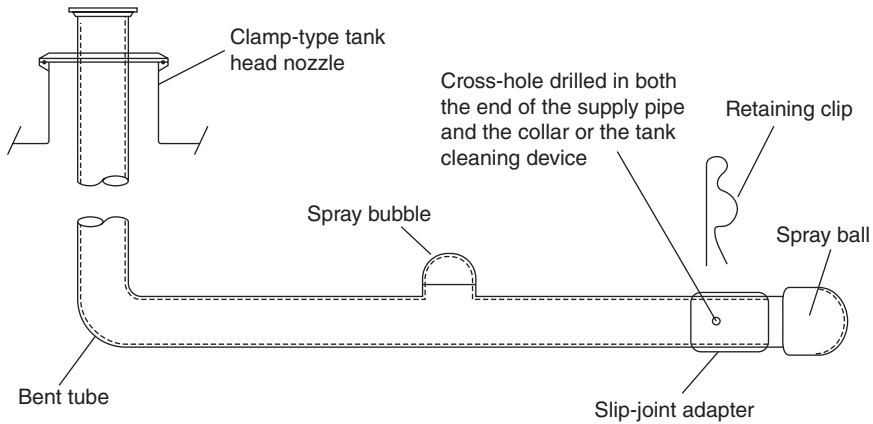
**Fig. 10.19** (a) Bubble spray devices may only extend 1.25–2 cm into a vessel (or pipe), or (b) they must be recessed ‘flush’, to prevent contact with the food product. The adaptor should be as short as possible, and no longer than 5 cm if the vessel wall is insulated. In both bubble spray applications, three or more holes provided in the spray supply tube, and proper clearances between the tube and adaptor make the assemblies self-cleaning. The piping supplying the solution can be continuously purged with filtered air to prevent product from entering the annular space. The tube adapter is sloped with a 3° pitch for free draining when the tank is emptied (3-A, 2003).

spray patterns onto the equipment surfaces via the directionally drilled holes. Bubble spray devices are used in tanks, equipment and ductwork, where the spray device must be positioned so that it cannot come into contact with the food product. Special fittings are used to insert bubble-cap sprays into a line or piece of equipment. Alternatively, depending on how far up they then need to propel the cleaning solution, they may only extend 1.25–2 cm into the vessel or pipe.

The number of tank head nozzles may be limited. In a vessel with only one clamp-type tank head nozzle, bubble arms (Fig. 10.20) or tee tubes can allow strategic placement of multiple spray bubbles to direct individual spray patterns in different directions. They are used in a variety of applications, such as reaching otherwise difficult-to-reach areas. A straight tube spray device is normally used for side entry to vessels if the head space is too small for a stationary spray ball. This can be used to clean the bottom side of a vertically mounted agitator. A bent tube spray device can be installed at any location providing the same coverage as multiple spray heads (cf. Fig. 10.34(b)). All these tube spray devices can be inspected and cleaned when removed via tri-clamp connections or slip joints. However, it is more difficult to remove all debris from them than it is in removable spray balls (Seiberling, 1997; Franks and Seiberling, 2008).

#### *Stationary ‘cluster’ spray device*

A stationary ‘cluster’ spray device (Fig. 10.21) is a non-spherical multi-nozzle spray assembly, made of polytetrafluoroethylene (PTFE), polyvinyl



**Fig. 10.20** Bent tube spray device with a spray ball attached to the end, by a slip-joint and retaining clip connection, and provided with a spray bubble for directional cleaning.



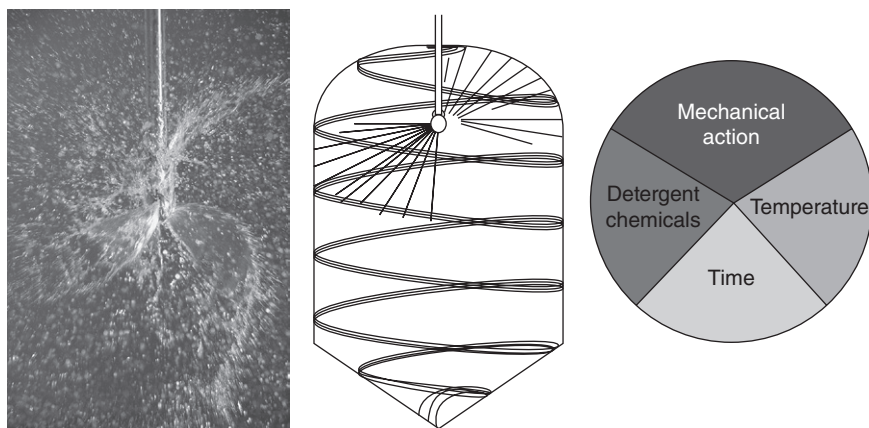
**Fig. 10.21** Stationary 'cluster' spray device provided with bore holes flush with the thick wall of the body (courtesy of Delavan Spray Technologies, Ltd).

chloride (PVC), polyvinylidene difluoride (PVDF), stainless steel or alloy. The device is either provided with easily removable screw mounted nozzles (solid cone, solid stream or spiral-type nozzles), or just contains boreholes drilled in and flush with the thick-wall of the body. Owing to the absence of threaded screw-mounted nozzles and the lack of sharp corners, the latter, flush type is the most hygienic and suitable for the food industry. The former spray device, with screw-mounted nozzles, should not be used in the food industry, unless these are removed after cleaning the tank. Every 'cluster' spray device must be equipped with a lower drain hole, to ensure liquid is completely drained. Static 'cluster' spray devices are used to remove (slightly) soluble non-sticking residues on interior surfaces of small tanks

with a simple rinsing action. These are installed on a supply pipe, in the top, at the bottom or in the sidewall of the vessel, equipment or tank via a threaded connection and produce a  $180^\circ$  (downward or upward),  $\leq 270^\circ$  (downward or upward) or  $360^\circ$  spray pattern. Several of these cluster spray devices can be installed at several tank depths on the same supply type, one below the other (Moerman and Leroy, 2002).

### 10.8.2 Rotary spray devices

Rotating spray devices are fluid (or occasionally motor) driven cleaning devices. They consist of either a rotating disc, or a ball or ring with strategically drilled holes, ports or slots that rotates around just one axis. The flow is concentrated into a small number of sprays that have high radial velocity, resulting in more impact on the area where the fans or droplets hit the tank wall. The rotating fan optimizes the distribution of cleaning fluid by ensuring that all interior tank surfaces within the impact pattern are fully covered. The increased turbulence in the liquid film running down the walls causes higher wall shear stress  $\tau_w$  that further helps to loosen residues. Hence, mechanical action is provided by both the enhanced impact of the cleaning fluid hitting the wall and by the gravity-assisted low to medium turbulent ( $2100 < Re < 6000$ ) flow of the cleaning solution on the surface (Fig. 10.22). Rotational controlled rotary spray devices may be used to remove medium insoluble soil types. Similarly to spray balls described above, rotary spray devices can act as strainers. Hence, pre-filtration of recycled cleaning solutions is required to remove trapped debris (Franks and Seiberling, 2008).



**Fig. 10.22** Rotating spray devices optimize the distribution of cleaning fluid by ensuring complete coverage, on impact, of all interior tank surfaces, while increasing the turbulence of the liquid film running down the walls (courtesy of Alfa Laval Tank Equipment A/S).

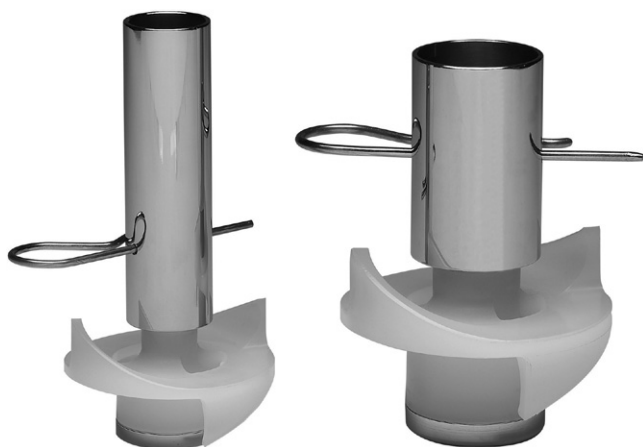


*Free-spinning rotary spray devices*

Free-spinning spray balls, ring-washers and spinners are reactionary force driven. The water streams, leaving the nozzle orifices as a spray, generate the reactionary forces necessary to produce and further maintain the rotary motion. Disc washers, however, are caused to rotate by the impact of cleaning solution on a disc. Free-spinning rotary spray devices usually roll on stainless steel roller bearings, as these promote fast spinning. Rotary spray balls can be fixed in any position within a vessel, equipment or tank. However, they require two rows of roller bearings to prevent blockage caused by their own weight (especially in sideward position). Blockage typically occurs in free-spinning rotary spray devices with one single row of roller bearings, that are prone to corrosion. Spray ring, disc washers and also some rotary spray devices make use of slide (usually PTFE) and/or hydro-bearings.

- **Rotary spray ball:** this cleaning device consists of a compact spray ball, made of sanitary polished stainless steel 316/316L or alloy, sometimes egg-shaped, with drilled holes or extended nozzles over the whole or a fraction of the ball. The ball rotates around one axis, moved by the reactionary forces caused by the solid fluid streams exiting the nozzle tubes or extended nozzle orifices. These solid fluid streams have much higher impingement effect than the full cone sprays produced by stationary spray balls. One disadvantage is that soil may accumulate at the roller bearing level, and soil or scale can block orifices. Holes must be regularly inspected for blockage, and a drain hole should be provided for self-drainage. If the supply comes through a tank head nozzle, one nozzle may be directed onto the surface of the supply body and the supply line, to improve self-cleaning of the rotary washer. Then the water directed up along the supply line and hitting the top of the tank will fall down as a free-falling film on the supply line (Moerman and Leroy, 2002).
- **Disc washer (spray deflectors):** a disc washer (Fig. 10.23) is a cleaning device in which the cleaning solution is directed through a series of holes onto the curved surface of a saucer-like disc, in order to rotate that disc around a static body attached to the liquid supply tube, to provide a cloud of fast moving, high-energy droplets to hit the tank surface. They can be positioned in the vessel, equipment or tank at any angle but are usually in the top or at the bottom of the vessel or equipment, secured to a vertical inlet tube by means of screw (although these are unhygienic), weld-on or clip-on connections.

However, these cleaning devices should only be considered for very simple and small applications. Disc-type spray deflectors tend to move slightly or bend under expansion, such that the distribution of the cleaning solution often becomes one-sided, leaving the other segment of the vessel uncleaned. As the saucer-like disc may deflect spray in an



**Fig. 10.23** Disc-type spray deflector (courtesy of Breconcherry, acquired by GEA Tuchenhausen GmbH).

irregular manner, cleaning solution often misses the upper and lower parts of the tank. Moreover, proper cleaning of the inlet sleeve of these cleaning devices is often difficult. Although the clogging risk is low, water scale and rust particles can cause these devices to stick. The disc is usually designed inverted to improve self-drainage (Tamplin, 1990; Moerman & Leroy, 2002).

- Rotary spray ring devices: a rotary spray ring washer (Fig. 10.24(a)) usually consists of a solid plastic ring (PTFE, PVDF, polypropylene (PP)), with multiple slope-wise drilled holes, that rotates over a thin liquid film (hydro-bearing) around a plastic or stainless/alloy static body attached to the liquid supply tube by a threaded or clip-on (locking pin) connection. There are cleaning devices on the market with a spray ring made of stainless steel 316(L) requiring a PTFE or polyether ether ketone (PEEK) slide bearing for smooth rotation (minimum friction and wear) around its stainless steel/alloy body. Common spray patterns are 360° all around, 180° (downward or upward) and 270° (downward or upward) in all possible positions. The spray ring may jam because of dirt, or at high rotation speed if the pressure is too high (Moerman and Leroy, 2002).

To simplify cleaning and maintenance, types that allow detachment of the spray ring from the nozzle body are preferred. All plastic types are excellent for use in corrosive environments at operating temperatures of 95–140°C. They are suitable for rinsing easily removable residues in small tanks.

- Spinner (slotted swirling fan rotary spray device): a spinner (Fig. 10.24(b)) is a cleaning device made of stainless steel or alloy. The reaction force of the cleaning water sprayed out of the slots or flat-shaped gaps



**Fig. 10.24** Reactionary force driven tank cleaning devices: (a) rotary spray ring washer consisting of a solid plastic ring with multiple slope-wise drilled holes that rotates over a thin liquid film (hydro-bearing) around a plastic or stainless/alloy static body (courtesy of Lechler GmbH); (b) free-spinning slotted swirling fan rotary spray device (courtesy of Scanjet Systems AB).

of a rotating sphere rolling on two ball bearing rows provides a rotating fan-like cleaning action (swirling and surging impact). They may rotate in any position but, with time, wear to the roller bearings can cause the rotary spray device to become blocked under its own weight. Before installation and during operation, users must check that the rotating component is working properly. A spinner, placed into a tank through a small flange hole, can be installed at various depths, connected by means of a clip-on, weld-on or threaded connection at a stainless steel lance (316 or 316L). These cleaning devices are excellent for vessels fouled by flaky and sticky soil, because the centrifugal forces generated when the spinner rotates can easily sweep the flaky material out of the rotating sphere via these slots. A slot/flat-shaped gap in the lower part of the sphere facilitates complete draining of the cleaning/rinsing solution laden with flaky soil out of the spray ball. This makes spinners an excellent substitute for static and rotary spray devices covered with bore holes that accumulate flaky material at the inside due to their strainer effect (Moerman and Leroy, 2002).

*Rotational controlled rotary spray devices*

These are momentum-driven tank cleaning devices that have a built-in speed reduction mechanism. When pressure increases beyond  $P_{crit}$ , this suppresses the rate of rotation of the rotary component. Usually this category of rotary spray devices have plastic bearings (PTFE or PEEK) combined with other steel components. These bearings can normally limit the rotational speed, at least until they begin to wear and loosen. Because the PTFE can deform under high-pressure or high-temperature conditions, some manufacturers offer special materials, e.g. PEEK or PDVF, for such applications to avoid failing of the bearings.

- Rotational controlled rotary spray balls (Fig. 10.25(a) and (b)) look similar to the free-spinning rotary spray balls but they have a drive system preventing high-speed spinning beyond the critical pressure limit. Because these spray balls rotate at a constant speed, they maintain their cleaning power. This can be further increased by increasing nozzle pressure. Solid streams impinge with higher impact force onto the tank

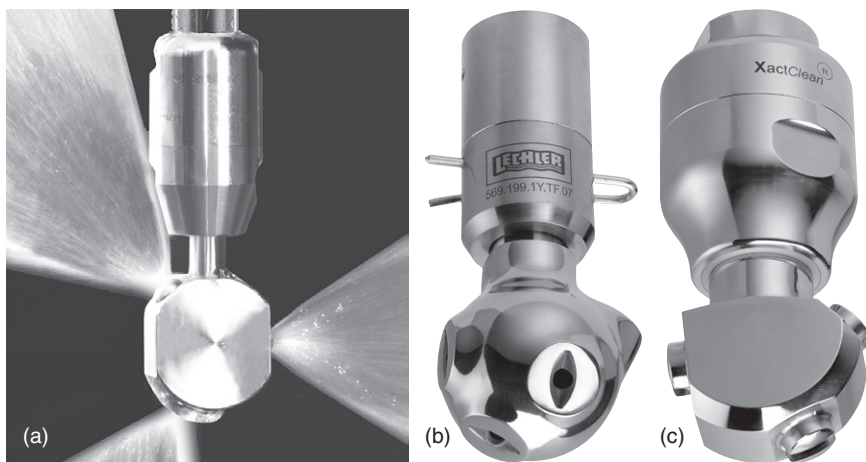


**Fig. 10.25** Rotational controlled rotary spray balls (a and b) and rotary spray rod (c) (courtesy of Spraying Systems Co.).

wall. The result is better cleaning power, faster cleaning cycles and lower volumes of cleaning solution required. Instead of a rotating spray ball, other rotating non-spherical multi-nozzle spray assemblies (e.g. a rod) (Fig. 10.25(c)) are designed to fit into smaller tank openings. The rotary spray balls can be fixed in several positions within a vessel, equipment or tank. A constant speed rotary spray ball is usually secured to the supply pipe via its supply body and, although less hygienic, a screw connection can be used if the supply tube and tank cleaning device are removed from the tank after cleaning the vessel.

- Rotational controlled tank cleaning devices with elliptical spray orifices can use the momentum of the fluid flow to drive the spray device and maintain constant rotating speed with increasing pressure beyond the critical pressure limit. The differential speed reduction unit prevents ineffectual high-speed spinning at liquid pressures  $>P_{crit}$ . Typical examples include the Rokon™ from Spraying Systems, Co., which has stainless steel elliptical ‘cat eye’ spray orifices inserted in its rotating body (Fig. 10.26(a)); and the ACCUClean® (Fig. 10.26(b)) and XactClean® (Fig. 10.26(c)) from Lechler GmbH, each of which have elliptical discharge holes. Both produce flat- or sheet-type sprays.

The orifices may clog but can be manually cleaned with a brush and detergent, a wooden tooth pick or pressurized air. Metal tools cannot be used to clean the nozzle orifices, because they may damage them. When using chemicals the nozzles should be flushed with water

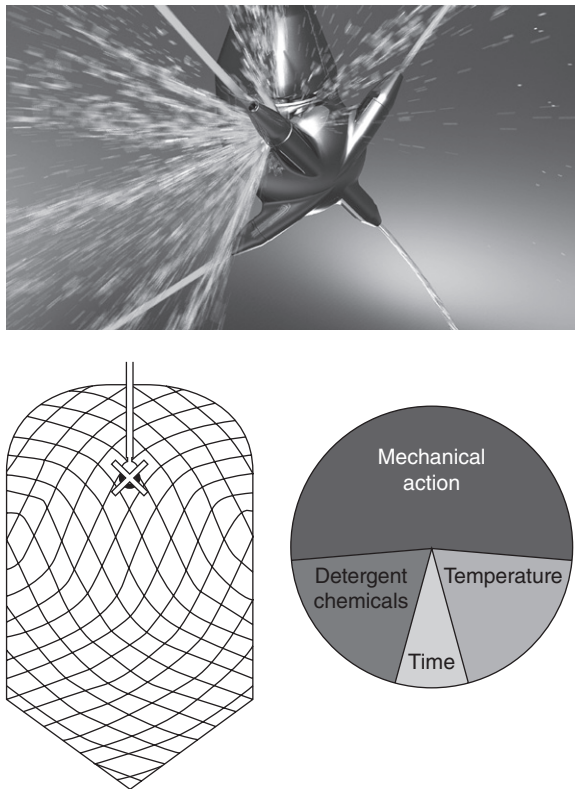


**Fig. 10.26** Other rotational controlled tank cleaning devices: (a) stainless steel Rokon™ with small stainless steel elliptical ‘cat eye’ spray orifice inserts (courtesy of Spraying Systems Co.); (b) ACCUClean®; and (c) XactClean® with elliptical discharge orifices (courtesy of Lechler GmbH).

after the cleaning operation. If the orifices are worn out, the rotating head of the tank cleaning devices should be replaced (Moerman and Leroy, 2002).

### 10.8.3 Rotary jet devices

Rotating jet devices are fluid or motor-driven tank cleaning devices. They rotate around their vertical axis (body) and horizontal axis (the nozzles), while producing synchronized solid water streams in a tight and thorough scouring spray pattern upon the internal structures and interior surfaces of a vessel, equipment or tank (Fig. 10.27). The cleaning solution hits with enough mechanical force to blast tough residue from the interior tank surfaces and explodes outwards with a force directly proportional to the initial force supplied (Fig. 10.28). The tangential force of the stream that



**Fig. 10.27** Rotating jet devices produce synchronized solid water streams that form a tight and thorough scouring spray pattern upon the internal structures and interior surfaces of a vessel, equipment or tank (courtesy of Scanjet Systems AB).





**Fig. 10.28** Rotary jet devices produce a concentrated stream of cleaning solution that is directed onto the surface to be cleaned. Cleaning occurs by direct impingement and by force of the stream that radiates away (the footprint area) from that point of impact (Courtesy of Gamajet Cleaning Systems Inc., acquired by Alfa Laval Group).

radiates away from that point of impact also significantly aids cleaning. Typically, at 60°C, the wall shear stress  $\tau_w > 1000 \text{ Pa}$  at a distance of less than 5 cm from the point of impact, decreases from 1000 to 40 Pa over a distance of 5 to 15 cm from the point of impact, to decline further down to a wall shear stress  $\tau_w < 10 \text{ Pa}$  at a distance of 20 cm from the point of impact. Shielded (shadow) areas with regards to the cleaning device can be scrubbed using deflective water jets. Finally, the mechanical action of the gravity assisted highly turbulent falling liquid film ( $30\,000 < Re < 70\,000$ ) provides additional cleaning (Alfa Laval Tank Equipment A/S, 2004; Jensen *et al.*, 2011).

Rotary jet devices with one to four, or even more, nozzles are usually fluid driven (turbine-type) or motor-driven (electric or pneumatic). There is also a piston-driven type (Breconcherry, acquired by GEA Tuchenhausen GmbH). Rotary jet devices provide high impact cleaning (usually 360° coverage) in tanks with volumes ranging from 15 to 1250 m<sup>3</sup>. Some rotary jet devices are designed to provide only directional 180° upward or downward impingement cleaning. A 180° downward spray pattern is appropriate for the cleaning of the sidewalls, bottom or internal structures in open-top vessels, equipment or tanks (Fig. 10.29).

Like many other tank cleaning devices, rotary jet devices cannot be installed in the tank suspended on a hose, because the reaction of the jet will move the machine from side to side. They should be rigidly mounted on a vertical supply pipe up or down using a clamp, weld-on or other connection. The use of threaded connections is common practice. However, they are less hygienic and must be able to be cleaned. Their design must



**Fig. 10.29** Some rotary jet devices provide only directional 180° upward or downward impingement cleaning. 180° downward spray patterns are appropriate for the cleaning of the sidewalls, bottom or internal structures of open-top vessels, equipment or tanks (courtesy of Spraying Systems Co.).

therefore include no more than eight threads per 2.5cm of length, with threaded grooves no deeper than their width, with thread radii no less than 0.4mm, and preferably with thread angles not less than 60° (in, e.g., American Standard Acme 60° Stub, or equal). Knuckle thread DIN405 is also allowed. However, the use of thread connections hygienically enclosed by seals is preferable so that the threads do not become product contact surfaces during dismantling operations.

A pre-filter or strainer in the drive mechanism is always required to prevent particulate clogging. Further, a nozzle to continuously clean the exterior of the tank cleaning machine is often provided. Moreover the intended leakage flow, which also assists in flushing the bearing elements, often serves to clean the outside of the tank cleaning machine (Moerman and Leroy, 2002).

## **10.9 Installation, positioning and operation of tank cleaning devices**

### **10.9.1 Operating parameters for tank cleaning devices**

Table 10.4 gives an overview of the operating considerations for different tank cleaning devices.



**Table 10.4** Tank cleaning devices: cleaning and wetting radius, required pressure, volumetric flow

	Cleaning* radius (m)	Wetting* radius (m)	Operating pressure (bar)	Flow rate* (l/min)
<b>Static spray devices</b>				
Spray ball	0.5–1.5 (max. 4)	1–3 (max. 6)	1–2.2	10–1400
‘Cluster’ spray device	1.2–3	2.4–3.5 (max. 5)	0.7–3.5	20–1500
<b>Free-spinning rotary spray devices</b>				
Rotary spray ring	0.5–2.5	1–3.5	0.7–6 (all plastic: max. 3.5)	15–1500
Dishwasher	0.5–2.3	2–3.5	0.7–4 (opt. 2–3.5)	25–245
Micro-spinner	0.25–0.75	0.5–1	1–5 (opt. 1–3)	15–50
Mini-spinner	0.75–1.4	1–2	1–7 (opt. 1–3)	50–130
Maxi-spinner	1–2	2.5–3	1–7 (opt. 1–3)	130–450
<b>Rotational controlled spray devices</b>				
Rotary spray ball	1.8–2.8	2–4.8	3–14 (opt. 3)	50–290
Rotary spray device with elliptical orifices	1.5–3.50	2–4.5	2–16 (opt. 3–7)	12–128
<b>Rotary jet devices</b>				
Motor-driven	2.5–15	4–40	3.5–350	5–900
Piston-driven	4.5–13.5	6–17.5	3–90 (opt. 4–9)	25–450
Turbine-driven	3–15	5–40	1.5–90 (opt. 3–10)	30–1100
Robotic-driven	4–6	7–10	3.5–300	20–55

\* Cleaning radius, wetting radius and flow rate depend on: (a) the pressure applied, (b) the number, design and size of the orifices in the spray body of stationary and rotary spray devices, or (c) the number, the length and the orifice size of (the) nozzles on the hub of the rotary jet devices.

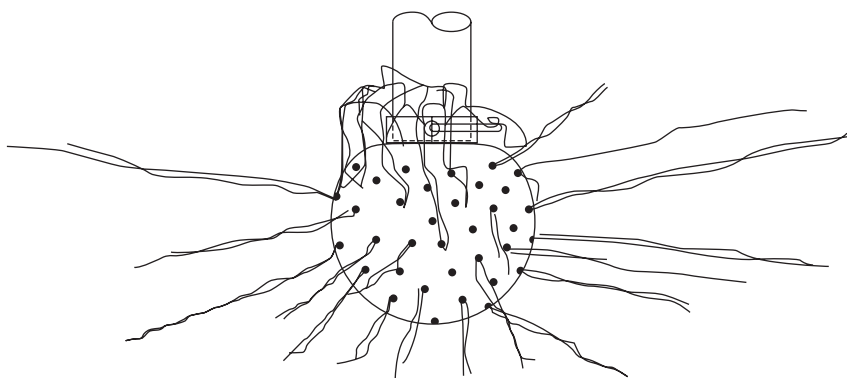
### 10.9.2 Hygienic installation of tank cleaning devices in vessels, large equipment or tanks

A tank cleaning device is commonly installed in a vessel, equipment or tank fixed on a supply down pipe using an internal connection. That supply tube is inserted into the vessel or equipment via a tank head nozzle, and is fixed onto this top nozzle with a tank connection. On the outside, the down pipe is connected with piping or a flexible hose that supplies the cleaning solution from a CIP-installation. Because hoses are easy to disconnect, they allow quick removal of the supply tube and tank cleaning device via the tank head nozzle, which is especially useful if less hygienic tank cleaning devices are being used.

*Internal connection*

Cleaning devices can be attached to the supply down pipe in several ways (Moerman, 2010):

- **Clip-on connection:** the supply down pipe is inserted into the slip-fit collar of the stationary or rotary spray device. A simple, wrap around, spring pin is placed in a cross-hole drilled in both the end of the supply pipe and the neck (collar) of the tank cleaning device. The water runs out through the small annular gap between the neck of the tank cleaning device and the exterior of the down pipe. This cleans the outside of the down pipe, which is inserted into the sleeve of the spray device, and the outer surface of the tank cleaning device (Fig. 10.30). This connection can not be used for rotary jet cleaning devices, because the reaction of the water jets may cause heavy vibration and bring the machine out of balance.
- **Tri-clamp connection:** this type of connection requires that both the sleeve of the tank cleaning device and the down pipe have a tri-clamp ferule. This serves to aid quick removal of the spray device. However, it does not offer the beneficial cleaning of the down pipe, the clamp (which is not hygienically designed) and the exterior parts of the connected tank cleaning device.
- **Weld-on (also known as butt-weld) connection:** permanently fixes the tank cleaning device to the supply pipe. This can be used if the tank cleaning device can be left in place, or if the complete assembly of pipe and washing device can be removed from the top.
- **Threaded inlet connections:** the collar of the cleaning device has a female thread to screw it onto the threaded male end of the supply pipe. Although less hygienic, this connection securely fastens the tank cleaning



**Fig. 10.30** The water circulating (escaping) through the small annular gap between the neck of the tank cleaning device and the exterior of the down pipe, cleans the outside of the down pipe, inserted into the sleeve of the spray device, and the outer surface of the tank cleaning device (Moerman and Leroy, 2002).

device on the supply pipe. Today, tank cleaning device manufacturers offer a thread connection with a gasket both inside and outside the pipe, to protect the thread completely from cleaning solutions and product. The problem that the screw inlet is less hygienic can be overcome if supply pipe and tank cleaning device can be easily removed from the tank after cleaning.

#### *Tank connection and external connection*

Standard tank connections include: weld-in connections where the down pipe is welded flush with and directly onto the tank; welding neck flanges of various types, including flat or grooved block flange, tri-clamp flange, flange fastened to the tank with a screw connection, or adjustable flanges. Adjustable flanges allow manual insertion of the tank cleaning device at different depths (by varying of the inside lance length) and angles (e.g. ball swivel adjustable flange) to achieve the best possible cleaning effect. Demountable tank connections facilitate removal of the supply pipe and tank cleaning device from the tank, so that they can be inspected and cleaned. This feature is especially recommended if less hygienic tank cleaning devices are used. If a permanently welded-in supply tube is used, the equipment design, construction and installation must allow access to the supply pipe for removal and re-installation of cleaning devices. The external connections used are usually butt weld, flange, tri-clamp, slip collar or half coupling type.

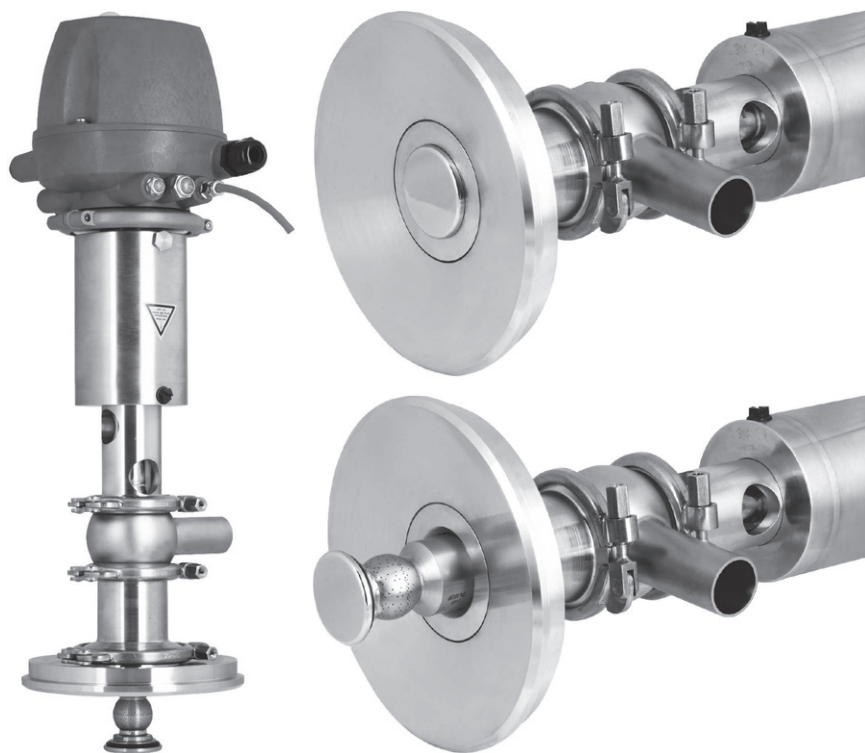
#### *Retractable tank cleaning devices*

Automated retractable tank cleaning devices (Fig. 10.31) can be installed in the head or the sidewall of the tank. The tank cleaning device is automatically extended when the cleaning cycle starts and retracted when it is complete. When the tank is in use, the cleaning device is completely sealed off from the product area, flush with the tank wall. Retractable tank cleaning devices are especially useful for cleaning internals in tanks which are normally submersed, such as the lower parts of agitators, dip pipes, sparger rings or piping, heating coils or baffles, where permanently installed tank cleaning devices deeper in the tank may contaminate sensitive products. This concept of 'tank cleaning device extension and retraction' allows the safe use of tank cleaning devices despite being considered less hygienic in product areas.

### **10.9.3 Installation of tank cleaning devices in vertical vessels**

#### *Radial positioning of tank cleaning devices in vertical tanks*

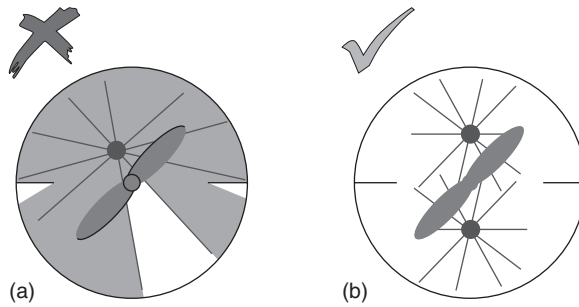
If a tank has obstructive internal structures (agitator, baffle plates, filling tubes, heating or cooling elements, gas spargers, foam breakers, vortex breakers, etc.) and numerous nozzles in the head or wall of the tank, one stationary or rotary spray device cannot effectively clean the whole



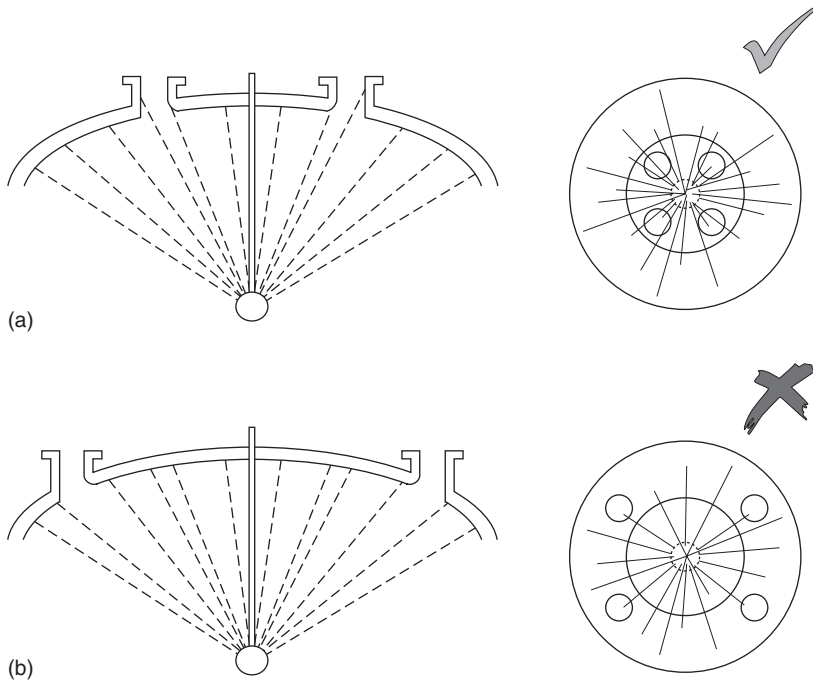
**Fig. 10.31** When retracted, the tank cleaning device is completely sealed off from the product area, flush with the tank wall. To start a cleaning cycle, the tank cleaning device is extended into the product area (courtesy of GEA Tuchenhausen GmbH).

interior. In Fig. 10.32(a), the agitator axis and baffle plates result in shadow areas and prevent direct impingement of the cleaning nozzle fluid sprays on these areas. They also block cleaning solution from striking the far side of the element. Therefore a suitable number of correctly positioned stationary and rotary spray devices must compensate for this shadowing effect to provide complete coverage. As a general rule, the number of stationary and rotary spray devices should at least match the number of baffles (Fig. 10.32(b)), and an additional stationary and rotary spray device is required for each extra internal structure in the tank that creates shadow areas.

The top nozzles in the head or the dome of the vessel and the annular space formed around the agitator shaft are also difficult to clean. The top nozzles should be positioned as close to the centre as possible so that a tank without internals may be cleaned with just one tank cleaning device, positioned in the middle of the vessel, that can spray enough liquid into each nozzle (Fig. 10.33(a)). If the top nozzles in the tank head are too far



**Fig. 10.32** (a) Top view of a tank with baffle plates and agitator which obstruct the sprays from hitting the surfaces behind. (b) Multiple spray devices are installed in suitable positions to compensate for the shadowing effect and to provide complete spray coverage.



**Fig. 10.33** (a) Top nozzles very close to the centre of the tank head allow a tank without internals to be cleaned with one stationary spray, rotary spray or rotary jet device (positioned in the middle of the vessel) that may spray enough liquid into each nozzle. (b) With tank head nozzles located further from the centre of the tank head, one central stationary and rotary spray device is not sufficient to clean these tank head nozzles effectively. Rotary jet devices can be used to clean shielded areas, with deflective water jets (Moerman, 2010).

from the centre of the tank head, a single stationary or rotary spray device in the middle of the vessel cannot clean these sufficiently (Fig. 10.33(b)). In that case, two or more cleaning devices (stationary and rotary spray devices) should be positioned in a circle one-quarter of the distance of the internal tank diameter from the centre of the tank (Fig. 10.34(a)). With tank head nozzles located even farther from the centre, these cleaning devices (stationary and rotary spray devices) should be located in a circle at a distance one-third of the internal tank diameter from the centre of the tank, especially in a tank with wall mounted baffles (Fig. 10.34(b)). If rotary jet devices are used, areas shielded from the cleaning device can be scrubbed thanks to deflective water jets. Hence, one higher impact tank cleaning device can replace several stationary or rotary spray devices to clean the roof area around the down pipes that supply cleaning solution. One jet of the rotary jet device may be directed upwards.

To facilitate the cleaning process, all top nozzles (in the head or the dome of the vessel) can also be positioned at one side of the vessel. The tank cleaning device (stationary and rotary spray device) can then be positioned in that half of the tank head, at a distance one-quarter to one-third of the internal tank diameter from the centre of the tank (Fig. 10.35).

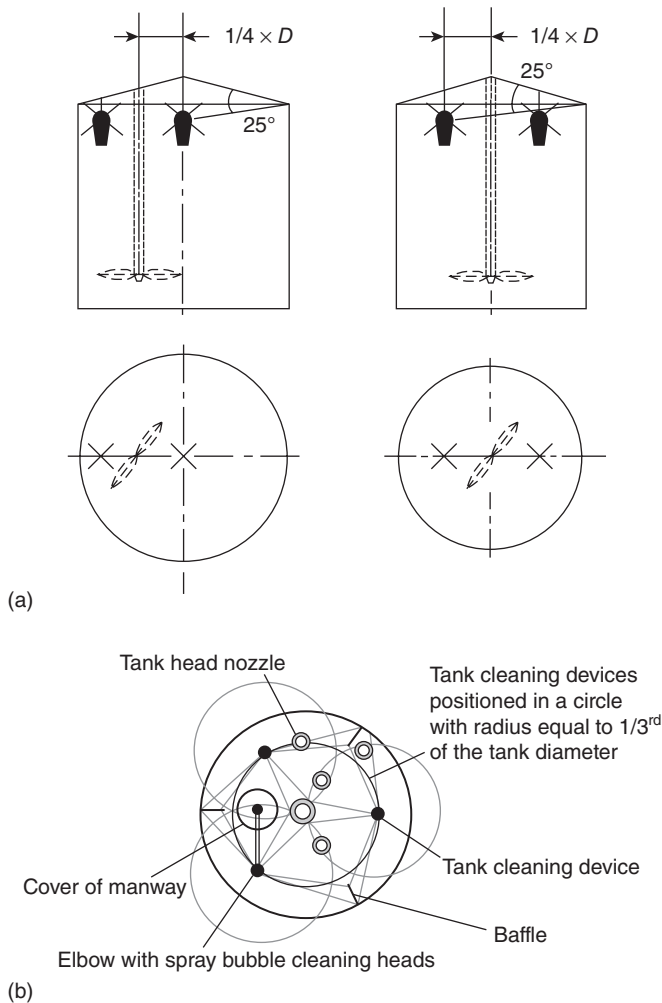
The number of top flanges should be kept to a minimum but must be sufficient to allow the processing operations to proceed and the installation of a sufficient number of tank cleaning devices. If only one top nozzle is left to install a tank cleaning device, then more complex cleaning devices can be used such as arms with bubble sprayers or tee-tubes with a spray ball at each end. Although mounting angled supply lines in a tank may provide better cleaning of shadow areas, that angled supply pipe may itself create shadow areas (Franks and Seiberling, 2008).

#### *Axial positioning of tank cleaning devices in vertical vessels*

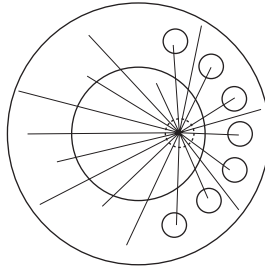
The number of recommendations for the installation depth of tank cleaning devices in vertical tanks practically equals the number of manufacturers and experts on the subject. The most commonly found is  $0.25 \times$  tank height  $H$ .

In a tank without internal structures, it is recommended to install the tank cleaning device on the centre line of the vessel. The required installation depth in a vertical tank can be calculated mathematically (Fig. 10.36).

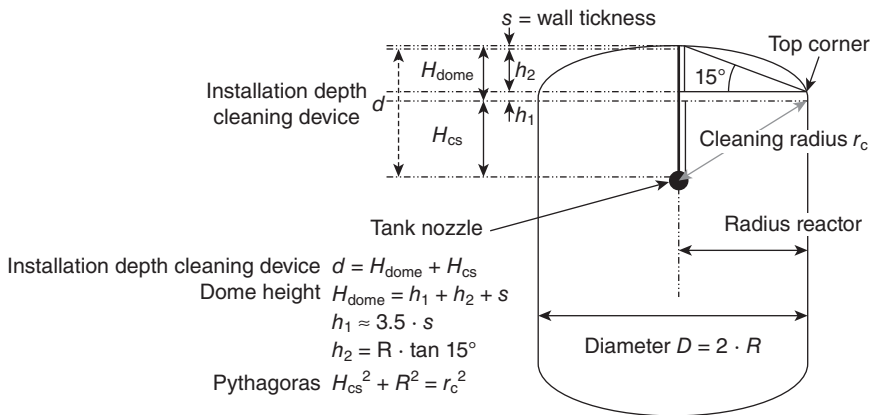
Tank ports in a wall of a tank can complicate a proper estimation of the installation depth. It is recommended to install the tank cleaning device below the side port in the tank wall (Fig. 10.37). If that side port is located in the lower parts of the tank, one might install the tank cleaning device deep in the tank below that port. However, if tank cleaning devices are immersed in the product, process fluids may enter the tank cleaning device when not in use and plug the holes. This will result in increased risk of contamination and poor soil removal, especially in the top corners of the



**Fig. 10.34** (a) If the top nozzles in the tank head are located at a considerable distance from the centre of the tank head, two or more cleaning devices (stationary and rotary spray devices) should be positioned in a circle at a distance one-quarter of the internal tank diameter, from the centre of the tank. (b) With tank head nozzles located even farther from the centre, stationary and rotary spray devices should be located in a circle at a distance one-third of the internal tank diameter, from the centre of the tank, especially in a tank with wall mounted baffles. The position of the stationary and rotary spray devices should cover the upper portion of each baffle and 'cross-chop' at the sidewalls and agitator collar. For top nozzles that might be the most heavily soiled, the cleaning device coverage should overlap. An extension arm fitted with a bubble is positioned directly under the centre of the manhole. The bubble can apply cleaning solution directly to the manhole cover, collar and fittings. In very large tanks, the same rules apply for rotary jet devices (Alfa Laval Tank Equipment A/S, 2004; Franks & Seiberling, 2008).



**Fig. 10.35** If all top nozzles (in the head or the dome of the vessel) are placed at one side of the vessel, the stationary and rotary spray devices should be positioned in that half of the tank head, off-centre at a distance one-quarter to one-third of the internal tank diameter from the centre of the tank.

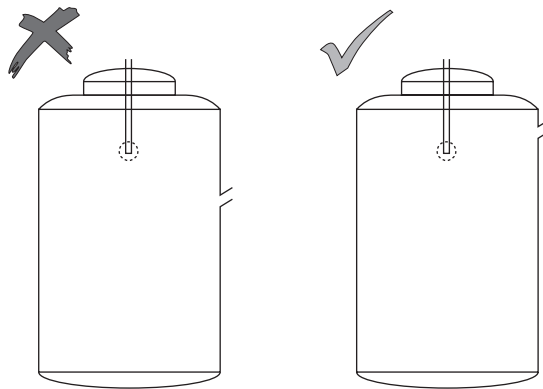


**Fig. 10.36** Illustration showing how the installation depth of a tank cleaning device at the centre line of a vertical tank can be calculated. The dome height  $H_{\text{dome}}$  (in m or cm) is either given by the vessel manufacturer, or can be approximately calculated with the equation  $h_2 = R \cdot \tan 15^\circ$ . Using Pythagoras' theorem, the height  $H_{\text{cs}}$  (which is about the depth of the tank cleaning device under the horizontal line drawn between the two top corners of tank) can be calculated. The cleaning radius  $r_c$  can be adapted by the food manufacturer, and is not necessarily equal to the maximum cleaning radius of the tank cleaning device. If food manufacturers want the fluid to have more impact in the top corners of the tank, then they can reduce the distance between the tank cleaning device and the top corner. However, they must still be aware that the tank cleaning device(s) should be installed in a position that allows for sufficient coverage of the top nozzles in the dome of the tank with the sprays of cleaning solution emitted by the tank cleaning device(s). With both  $H_{\text{dome}}$  and  $H_{\text{cs}}$  known, the installation depth  $d$  can be calculated (Moerman, 2010).

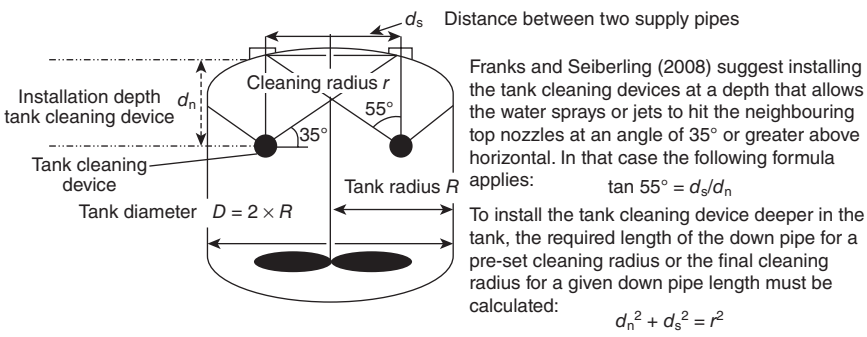
vessel. Hence, it is highly recommended to install side ports as high as possible, but still sufficiently low to allow correct measurements during process operations (Tamplin, 1990).

In a tank with internals, the recommendations for the depth of installation of the tank cleaning devices are somewhat different from those for a tank





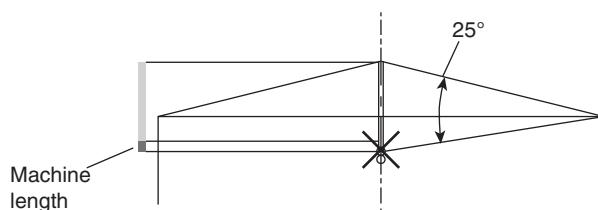
**Fig. 10.37** To prevent tank cleaning devices from being immersed in the product and to guarantee appropriate cleaning of side ports, side ports should be installed as high as possible but still sufficiently low to allow correct measurements of process parameters.



**Fig. 10.38** Franks and Seiberling (2008) suggest installing the tank cleaning devices at a depth where the spray streams directed at the top nozzles in the tank head have an upward vector component of 35° or greater above horizontal, allowing the spray to ricochet upward after hitting the target nozzle.

without internal structures. Franks and Seiberling (2008) recommend that fluid should hit the neighbouring top nozzles at an angle of 55° or less from the vertical (Fig. 10.38), which in fact is the down pipe supplying the cleaning solution to the tank cleaning device. Where head space restrictions and sensitive food products (in which the device must not be immersed) make installation of tank cleaning devices at that recommended depth impossible, a greater number of tank cleaning devices will be required.

Referring to Fig. 10.34(a), the installation depth of the rotary jet device is calculated by Alfa Laval Tank Equipment A/S (2004) as shown in Fig. 10.39.



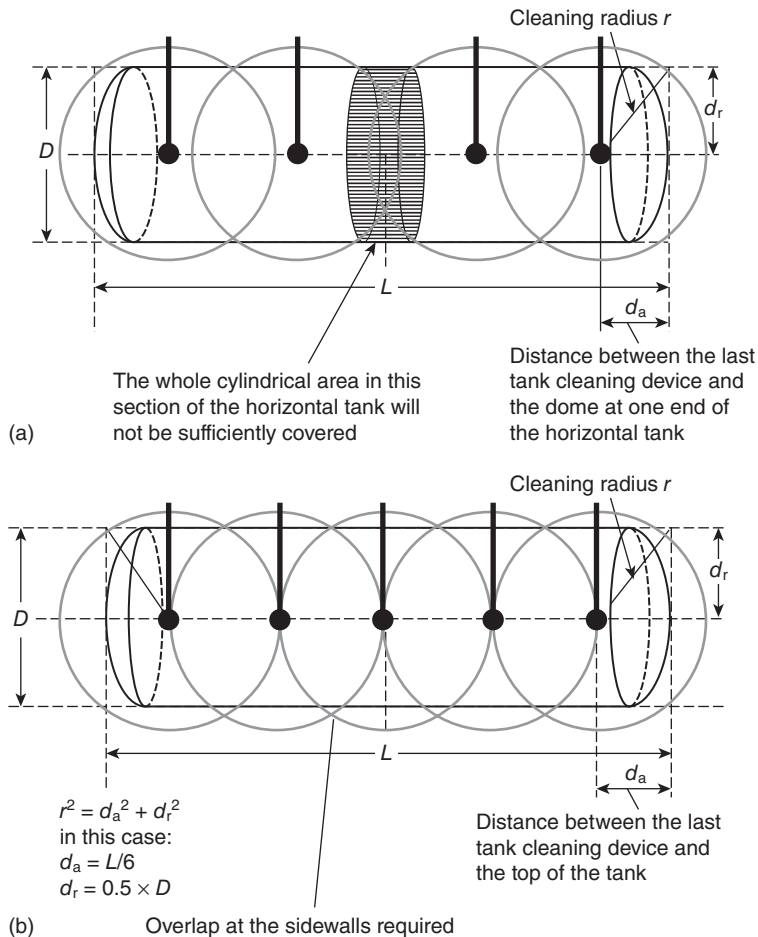
**Fig. 10.39** The installation depth of the tank cleaning device is calculated by Alfa Laval Tank Equipment A/S (2004) in the same way as was suggested for centre line installations of tank cleaning devices:  $\tan 25^\circ \times \text{largest horizontally cleaning radius [m]} - \text{machine length (between connection and nozzle) [m]}$ .

#### 10.9.4 Positioning of tank cleaning devices in horizontal tanks

##### *Number of tank cleaning devices in horizontal vessels*

Alfa Laval Tank Equipment A/S (2004) recommends installing an extra tank cleaning device when the length of the tank exceeds 0.5–0.8 times the cleaning diameter of the tank cleaning device(s). Tamplin (1990) uses Pythagoras' theorem to determine if a selected type of tank cleaning device installed in a given position at each end of the horizontal tank is able to clean the dome. Further, he suggests the use of a graphical approach to determine if there are enough cleaning devices in the horizontal tank and if they are correctly spread over the total length of the tank to allow for sufficient coverage of the whole tank area with cleaning solution.

Tank cleaning devices must produce water sprays or jets of sufficient throw length and impact to remove a given soil type. Firstly, the food manufacturer must determine which tank cleaning devices produce water sprays or jets that can meet these requirements. Tamplin (1990) then suggests using Pythagoras' theorem to calculate if the selected tank cleaning devices are correctly positioned at each end of the horizontal tank (Fig. 10.40(b)). The distance between the selected tank cleaning device and the corner of a rectangle circumscribing the vessel must be smaller than the minimum required cleaning radius for appropriate removal of that soil type. If it is not, then the cleaning device is too far from the tank end. Either the distance should be adapted or another cleaning device that produces water sprays or jets with a throw length and impact that exceed that distance should be selected. Thirdly, the coverage of the tank area can be readily visualized on a scale diagram of the vessel (Fig. 10.40). To do this, for each tank cleaning device, cleaning circles set to the minimum required cleaning radius should be drawn with a compass. The vessel corners at the ends of the horizontal tank must always be cleared by the cleaning circles. Then cleaning circles must be drawn in the directions opposite to both dome ends. Figure 10.40(a) shows that four tank cleaning devices are not sufficient to cover the whole tank surface. A cylindrical area in the middle section of the horizontal tank will be poorly cleaned. Hence, an additional tank cleaning device (Fig. 10.40(b)) is required.



**Fig. 10.40** Identical tank cleaning devices installed at a depth  $d_r$  from the cylindrical tank roof must be uniformly spread over the total length  $L$  of the tank so that the end domes and the whole cylindrical section of the horizontal tank are covered.

#### *Installation depth of tank cleaning devices in horizontal vessels*

If the tank cleaning devices are submerged in the product, then they should be hygienically designed so that they are self-cleaning and self-draining, both internally and externally. Tamplin (1990) prefers to install stationary and rotary spray devices as high as possible in the tank, to achieve better coverage and distribution of cleaning solution on the vessel roof. Moreover, specific areas (top nozzles, manhole, annular space around down pipes, etc.) can be cleaned more effectively by direct impingement. Installation of stationary and rotary spray devices at considerable distance from the tank roof may result in poor soil removal in the corners of the vessel. The usual

recommendation for installation of stationary and rotary spray devices is  $0.25 \times \text{tank diameter } D$ , while rotary jet devices should be installed at a distance of  $0.35 \times D$  up to  $0.5 \times D$  from the tank roof. The long throw length and the higher impact of the water jets they produce allow adequate removal of soil from the tank head and vessel corners. There are varying recommendations, including, for example,  $0.23 \times \text{tank length } L$ .

## 10.10 Managing tank cleaning

### 10.10.1 Amount of cleaning solution required for proper tank cleaning

The amount of cleaning solution needed depends on several main factors. These include the type of tank cleaning device; the tank geometry; the presence of internal obstructions (agitators, dip pipe, baffles, etc.); the location of tank head nozzles and tank wall ports; the type of soil; the tank cleaning procedure (e.g. pulsed-flow cleaning); the tank draining capacity; and the factors in Sinner's circle (concentration and temperature of the detergent solution, coverage and cleaning time). The minimum flow rate must provide enough flow down the walls that the entire surface will be covered and the liquid cannot pull itself into channels with open voids. Either the flow rate per unit tank area or per unit tank circumference can be used to express the amount of cleaning solution required. There are numerous recommendations for the required amount of flow for appropriate tank cleaning (Table 10.5).

To determine the amount of cleaning solution required for the cleaning of tanks using spray balls, Tamplin (1990) has also made the recommendations listed in Table 10.6. The flow rate per unit tank circumference varies with the height of the vessel for vertical- and rectangular types, and with the length and the diameter of the vessel for horizontal types (Table 10.7).

Alfa Laval Tank Equipment A/S (2004) has demonstrated that rotary spray and rotary jet devices can clean vessels with 30% and 50% less cleaning solution, respectively. To determine the flow rates required for tank cleaning with rotary spray and rotary jet devices, the indicative values in Tables 10.6 and 10.7 must be multiplied with a factor of 0.7 and 0.5 respectively (Jensen *et al.*, 2011).

### 10.10.2 Proper drainage capacity

#### *Importance of suitable drainage*

In order to clean the tank sufficiently, the vessel must also be able to drain liquid at the same rate that it takes in liquid, via the tank cleaning devices. Proper drainage is required for several reasons:

- To prevent suspended solids removed by the cleaning process from settling at the tank bottom surface. A study by Salo *et al.* (2006a)

**Table 10.5** Recommendations for amount of cleaning solution for tank cleaning using spray balls according to different sources

Text source	Range l/min per m <sup>2</sup>	Range m <sup>3</sup> /h per m <sup>2</sup>
Christi (1999)	4–12*	0.24–0.72
Seiberling (1997)	8.2–12.3*	0.5–0.74
Welander (2002)	8.2–12.3**	0.5–0.74
Welander (2002)	16.4–20.5*	0.985–1.23

Text source	Range l/min per m circumference	Range m <sup>3</sup> /h per m circumference
Tamplin (1990)	24.8–49.8**	1.5–3
Tamplin (1990)	17.4–24.8***	1.04–1.5
Christi (1999)	31.1–37.2**	1.87–2.23
Welander (2002)	31.1–49.8**	1.87–3
Greene (2003)	11.2–12.7 ( <i>r</i> ° cleaning solution = 80 °C)	0.67–0.76
Greene (2003)	32.4–39.2 ( <i>r</i> ° cleaning solution = 20 °C)	1.95–2.35
Lorenzen (2005)	30–50	1.8–3
Franks & Seiberling (2008)	31.1–37.2**	1.87–2.23
ASME (2009)	31.1–37.2**	1.87–2.23
Jensen <i>et al.</i> (2011)	33.3	2

\* Horizontal, square or rectangular tanks, tanks with complex shapes, and vessels with baffles, agitators and other projections.

\*\* Vertical tank without internals.

\*\*\* Horizontal tank (circumference = 2 × (tank length + tank diameter)).

**Table 10.6** Spray ball flow rates required for suitable cleaning of vessels (Tamplin, 1990)

Type of vessel	Total flow rate required (l/min)
Vertical vessel	(vessel diameter × $\pi$ ) × circumferential flow rate (l/min per m)
Horizontal vessel	2 × (vessel diameter + vessel length) × circumferential flow rate (l/min per m)
Rectangular vessel	2 × (vessel length + vessel width) × circumferential flow rate (l/min per m)

demonstrated that cleaning an inclined stainless steel surface by rinsing with plain tap water at a volumetric flow rate that is sufficient to cover the surface is very difficult. Some 70% of the surface area remained dirty. Therefore, the flow across the tank bottom surface must be sufficiently high to quickly remove the suspended solids from the tank. If not, the product and cleaning fluid residues become difficult to rinse out. This

**Table 10.7** Recommended circumferential flow rate (l/min per metre circumference) required for tank cleaning by means of spray balls (Tamplin, 1990)

Height or length (m)	Horizontal cylindrical*			Vertical vessel**	Rectangular vessel***
	Diameter (up to 1.5 m)	Diameter (up to 3 m)	Diameter (up to 4.5 m)		
3	17.4	19.9	19.9	24.8	24.8
7.5	19.9	22.4	22.4	29.8	29.8
15	22.4	22.4	22.4	37.25	37.25
24	22.4	24.8	24.8	49.8	49.8

\* Circumference =  $2 \times (\text{vessel length} + \text{vessel diameter})$ .

\*\* Circumference = vessel diameter  $\times \pi$ .

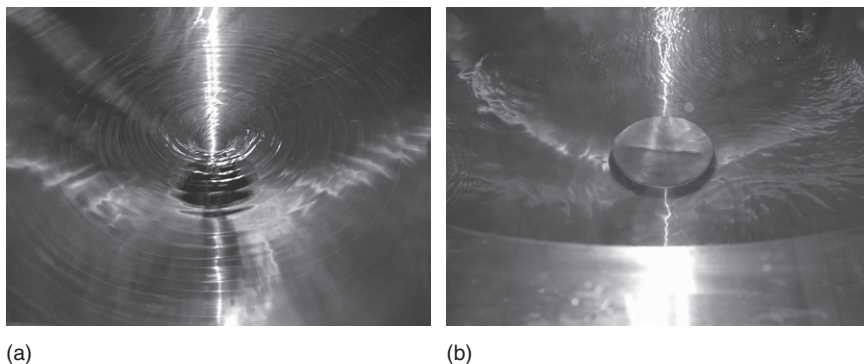
\*\*\* Circumference =  $2 \times (\text{vessel length} + \text{vessel width})$ .

results in bigger mixing zones in the CIP circuit. Separation of individual cleaning steps will then be more difficult and chemical losses will increase.

- To avoid deposition of soil (e.g. fat) on the tank wall at the liquid–air interface. This would cause a ‘bathtub’ ring (dirt liquid ring) to form (Greene, 2003).
- To allow the sprays or jets of the tank cleaning device(s) to hit the tank wall and bottom surface directly. If the drainage is insufficient, the bottom of the vessel will be harder to clean, resulting in longer cleaning times.
- To quickly remove foam from the tank. If the outlet is too small, then more time and more rinse liquid will be required.

### *Vortexing phenomenon*

The CIP solution return system should be designed to maintain a very small puddle of liquid in the bottom of a vessel. A puddle 50 mm deep in the vessel being cleaned is acceptable in order to prevent the CIP return pump from binding air. Usually a CIP return pump is selected with a capacity that is 10–25% higher than the CIP supply pump because the CIP return pump has to handle liquid and also a lot of air. The CIP return pump may have to pump a 50/50% air/water mixture. This is especially true if vortexing takes place, which can prohibit proper tank draining, ultimately causing flush, wash and rinse solutions to accumulate in the vessel. A vortex, which is a common problem in round bottom tanks with centre outlet, partially blocks the exit area, restricting the flow, and trapping air in the return stream (Fig. 10.41(a)). That air may subsequently cause the CIP return pump to become ‘air-bound’. Once the CIP return pump is air-locked, flow in the CIP return line will soon stop and cleaning or rinsing solution will accumulate in the process vessel.



**Fig. 10.41** (a) Vortexing may prohibit proper tank draining, ultimately meaning that flush, wash and rinse solutions start to accumulate in the vessel. (b) Vortex formation can be prevented by installing a flat vortex breaker plate (courtesy of Gabe Miller, Sani-Matic, Inc.).

#### *Vortex reduction and sizing the tank outlet*

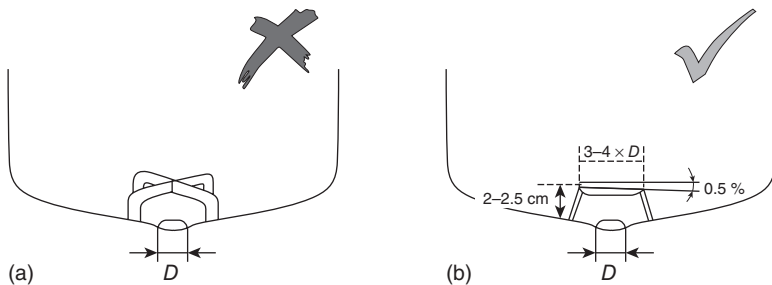
Vortexing of liquid at the bottom outlet may be prevented in several ways:

- Asymmetrical positioning of the tank outlet at the lowest point.
- Application of slant bottom tanks that have a flat bottom pitched to a pod and tank outlet valve, each mounted on the sidewall, provided that the process permits such a design. The bottom of flat vessels should not pitch less than 2% from rear to front outlet (from high to low point), and no less than 4% from side to centre outlet for vessels with a dish or cone-shaped bottom. Table 10.8 gives an overview of the tank outlet diameter required for proper drainage of fluids out of the tank.
- Installation of one baffle may reduce vortexing, although its effect will be limited. Proper baffle design needs sufficient space between the bottom of the baffle and the vessel base for them to be more easily cleaned. This means that baffles cannot prevent vortexing in puddles of liquid below the lowest part of the baffle during drainage.
- The size of the outlet and CIP return piping should be decided based on avoiding vortexing and minimising holdup. This usually leads to bottom outlet lines larger than would otherwise be required for the process.
- Vortexing can be prevented by installing a flat vortex breaker plate (Fig. 10.41(b)). That plate (Fig. 10.42(b)) should be approximately three or four times the size of the outlet diameter, and be installed at a height of no more than 2–2.5 cm above the tank bottom to ensure appropriate cleaning and wetting of the underside of the plate. It is recommended to pitch the plate with a slope of 0.5–1° for the flat surface to drain. The vortex breaker plate should have a round profile at the underside. The plate is commonly supported with at least one ‘J-hook’ support. These

**Table 10.8** Minimum inside diameter of the tank outlet required to guarantee proper drainage of the tank cleaning solution which is supplied by spray balls to a tank with vessel aspect ratio ( $H/D$ ) = 2

			Required outlet pipe with reference to ASME- BPE-2009 (inch)		Required outlet pipe with reference to DIN11850 Range 2	
Volume vessel (l)	Tank diameter (m)	Tank circumference (m)	Delucia (2001)		Moerman (2012)	Lechler (2011)*
			Moerman (2012)	Lechler (2011)*		
500	0.68	2.15	1.5	2	DN32- DN40	DN50
1000	0.86	2.70	1.5–2	2–2.5	DN40- DN50	DN50- DN65
2000	1.09	3.40	2–2.5	2.5	DN50	DN65
5000	1.47	4.60	2–3	3	DN50- DN65	DN65- DN80
10 000	1.85	5.80	3	3–4	DN65	DN80- DN100
20 000	4.25	13.35	3–4	4	DN65- DN80	DN80- DN100

Note: The recommended drain outlet is calculated with respect to a spray rate of respectively of 31.125l/min per m of tank circumference (removal of soluble soil) and 37.35l/min per m of tank circumference (insoluble heavy soil-type) (Moerman, 2012). These calculations correspond very well with the recommendations of Delucia (2001). However, Delucia does not take sufficiently into account the possibility of air entrainment in the return stream. Contrary to Delucia's assumption that little air is entrapped in the return stream, the drainage flow rates under gravity given by Lechler (2011) reflect much better the reality. Their data are about half the drainage flow rates proposed by Delucia, which corresponds with the suggestion of Seiberling (1997) that a return line generally contains a 50/50 air/water mixture.



**Fig. 10.42** (a) Vortex breakers of the X-cross-section type are ineffective as they generally produce four smaller vortices, which influence the return flow in the same manner as one large vortex does. (b) Installing a flat vortex breaker plate approximately three or four times the outlet diameter, at a height of 2–2.5 cm above the tank bottom is more effective. It is recommended to pitch the plate with a slope of 0.5–1° to drain the liquid from the flat surface.



are 1.25 cm round stainless steel bars welded hygienically and flush with the tank bottom and the plate. 'X-cross-section' type vortex breakers (Fig. 10.42(a)) are ineffective. They generally produce four smaller vortices that also impact on the return flow. The plate vortex breaker, however, can enable CIP return flow at the required rate with only 10% as much solution in the vessel as is required with no vortex breaker. Further, the puddle during CIP recirculation can be as little as 12–20 l in large tanks at flow rates of 300–380 l/min (Seiberling, 1997).

Another way to avoid collection of pools of liquid in the bottom of the tank is to supply cleaning solution intermittently. After a short time of spraying the supply valve is closed and the tank is emptied before spraying is resumed. In burst cleaning, regular bursts of cleaning solution are interspersed with draining periods. Pre- and post-rinsing must always be done in three or more successive bursts for 20–45 s at carefully timed intervals, so that there is enough time for drainage and vessel collapse does not occur (Tamplin, 1990; Seiberling, 1997).

### 10.10.3 CIP return flow

Drainage and return flow are strongly connected. Cleaning and rinsing solutions can be removed from vessels being spray cleaned in several ways (Seiberling, 1997):

- Gravity allows proper drainage and return of solutions from the process vessel, if the vessel is one or more levels above the CIP system, and if the tank outlet valves and return system piping are sufficiently large. The return piping should be pitched at a slope declining 2% to the CIP recirculating unit (CIP installation).
- A product pump and/or an additional CIP return pump is commonly used to drain and return solutions to the CIP system.
- CIP return pumps are often used if gravity alone is insufficient for proper tank drainage and CIP return flow to the system. A return pump is needed to overcome the friction losses in the CIP return line. The CIP return pump must be positioned directly below the process tank. If the return line to the return pump slopes upwards toward the tank being cleaned, then air can escape the return pump and return to the tank being cleaned. Alternatively, an air-relief valve at the pump inlet may be installed, especially if the return lines to the CIP systems are long. Low-speed (1750 rpm) return pumps are usually preferable to high-speed (3450 rpm) ones as the latter become more easily air-bound. This causes the high-speed return pumps to cavitate.
- An eductor can help the CIP pump to return both air and water to the air separation/recirculation tank, where the air may disengage from the fluid.

- An eductor alone, without a CIP return pump, can even guarantee proper return flow if the return piping is sufficient in size and not too long.
- The process tank can be pressurized so that the flow can overcome resistance in the outlet nozzle and valve, and move quickly through the CIP return piping. However, it is difficult to control and sustain a pressure that is sufficient to maintain the minimum liquid level required at the nozzle entrance. If the pressure is too high, additional entrainment of air will occur.

#### 10.10.4 Cleaning the bottom-outlet and bottom-valve

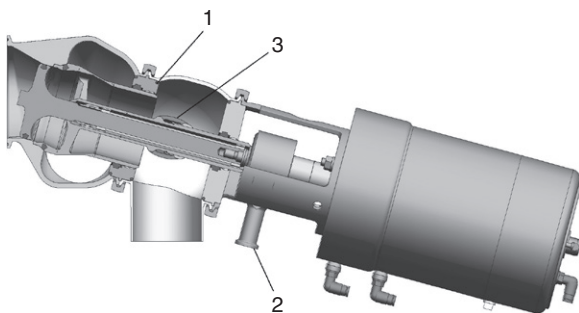
To clean the outlet line, the vessel can be flooded to a height of about 15 cm and drained out, as long as no tide mark remains. This is especially useful with sidewall mounted tank outlets in slant bottom tanks, where flooding also cleans and rinses the top of the outlet pipe (Tamplin, 1990).

Regardless of the type of bottom outlet valve, nearly all tank outlet valves require a short pipe to provide a connection. However, this results in a 'dead-leg', an area where contamination often occurs. A hygienically designed and cleanable bottom valve can solve many of these problems. This involves the following considerations:

- The internal volume of the bottom outlet valve should be kept to a minimum.
- All cavities and internals (e.g. valve stem) must be easily accessible for cleaning by CIP fluids and allow for complete drainage

Nevertheless, sufficient cleaning of the bottom outlet valve cavity is still very difficult. Repeatedly opening and closing the bottom valve during the cleaning sequence may help. If this technique does not work, and no alternative can be installed, dismantling and manual cleaning may be necessary.

At present, bottom outlet valves can be purchased with side ports to allow flushing of the body cavity. But according to the Pasteurized Milk Ordinance (PMO; FDA, 2011), the bottom outlet valve cavity must not be pressurized during cleaning when there is product in the tank. Experimental cleaning trials have shown that cleaning the bottom outlet valve cavity, even with stationary spray devices, is very difficult. In a sophisticated, automated form, a retractable or fixed mounted cleaning device positioned in a cleaning port is sometimes used to clean the inside cavity, the stem and the plug of the bottom outlet valve without pressurizing the cavity. However, the internals (e.g. valve stem) introduce shadow areas in the bottom valve cavity, so even that option is not completely successful. A patented solution with a rotating spray device fed with cleaning solution via a hollow valve stem (Fig. 10.43) can efficiently clean the bottom valve cavity without shadowing effects (Jensen *et al.*, 2011).



**Fig. 10.43** PMO mixproof valve for horizontal tank outlet: 1 sealing element, 2 liquid supply line for cleaning liquid and 3 rotating element (courtesy of Alfa Laval Tank Equipment A/S) (Jensen *et al.*, 2011).

#### 10.10.5 Venting of the tank

Atmospheric vessels must be equipped with a suitable permanent vent to protect them from internal pressure or vacuum damage during normal operation. The air vent must also prevent collapse which can be caused by a vacuum pulled on the vessel with a CIP return pump or by vapour condensation that takes place after rinsing with hot wash solutions at ambient temperatures (Fig. 10.44).

A perforated vent should have a free opening area equal to at least 1.5 times the area of the minimum vent opening in the storage tank. When a tank is rinsed with water that is much colder than the hot cleaning solution of the wash step, flash cooling takes place and the hot air will shrink suddenly to a volume that is only one-tenth, or even up to one-twentieth, of that volume. The shrinkage creates a vacuum that collapses the tank, unless the vent, manhole or openings allow the air to enter the tank at approximately the same rate of air volume decrease. Hence, during the cleaning cycle, a very large vent such as the manhole opening is required to accommodate this air flow, which is caused by sudden changes in temperature of very large volumes of air. Excessive loss of cleaning solution through the manhole opening must, however, be prevented. Tempered water, about 35°C, can be used for both pre-rinsing and post-rinsing to reduce the effect of flash heating and cooling.

#### 10.10.6 Further recommendations for suitable tank cleaning

To improve the cleaning of process vessels and their internals, the following actions should be taken:

- Tank hole covers should be opened before tank cleaning, thoroughly cleaned (including the gasket) and put back in place for CIP cleaning and disinfection of the tank.



**Fig. 10.44** Atmospheric vessels must be equipped with an adequate permanent vent to protect them from internal pressure or vacuum damage during normal operation. The air vent also must prohibit potential vessel collapse which can be caused by a vacuum pulled on the vessel with a CIP return pump or by vapour condensation that takes place after rinsing with hot wash solutions at ambient temperatures.

- During usual inspection and maintenance operations, certain factors should be checked. Cleaning devices must allow proper distribution of the cleaning solution, for example there should be no fouling, clogging or blockage of holes. The cleaning device must rotate properly (rotation can be hampered if ball bearing or bushings are worn). Atomization of the cleaning solution, which takes place if the delivery pressure is too high, should be avoided. To verify proper rotation of a rotary tank cleaning device, an electronic pressure sensor (Fig. 10.45) in the head or the wall of the tank can measure the changes in pressure on its surface as the spray or jet passes by. There should be regular undulations in the measurement at the same frequency as the nozzle's rotation. A cruder alternative would be to listen through the wall of the tank for the same pulsations, using a stethoscope or similar device.



**Fig. 10.45** An electronic pressure sensor located in the head or the wall of the tank can measure the changes in pressure on its surface as the spray or jet passes by. On the left is the SMW100 sensor of GEA Tuchenhausen GmbH; on the right, the Rotacheck sensor of Alfa Laval Tank Equipment A/S.

- Do not use more coverage than is necessary. To wash a tank head, use a design that only sprays in the required direction, so as not to waste cleaning power on parts that do not need it.
- The shadow areas that the agitator blades create can be minimized by running the agitator during the cleaning cycle. At the start of the CIP cycle, allowing a puddle of liquid to collect in the tank may support the cleaning of the underside of the rotating agitator. During rotation of the agitator, the blades may sweep liquid against the walls at the bottom of the tank providing some mechanical effect.

## 10.11 Automation

Today, most of the CIP stations, even small ones, are automated, or at least the control of the CIP operations is integrated into the automation system of the separate process machines. In the former case, the CIP station manages the whole sequence of cleaning steps. It functions like a domestic washing machine in that it passes through a pre-set programme of cleaning, rinsing and drying. In the latter concept, the automation system of the CIP station only controls the temperature and detergent/disinfectant concentration. Meanwhile the automation system for each separate process equipment controls the whole sequence of cleaning steps (i.e. the time for each path, opening/closing of valves, flow rate, etc.) (Rizoulières *et al.*, 2009).

Running a CIP process involves keeping track of hundreds of valves and operating them in different combinations and sequences. The best method for recording which combination is needed for a given purpose and setting that up as quickly as possible is using a microprocessor-based PLC. All the transmitters (such as flow meters and conductivity sensors) and all controlled objects in the CIP process are connected to the PLC, so that all the necessary information regarding temperatures, flows, pressures, valve positions, etc., can be fed into the control system. The PLC processes these input signals and sends out commands in a certain order to start or shut off the various control objects (pumps, valves and motors) involved in the controlled CIP process, so that the right conditions for the CIP process are satisfied. The controlled components send back acknowledgement signals confirming that the commands have been carried out. These feedback signals to the PLC are required to make the next step in the sequence to happen.

Each PLC has its own process areas to control. However, several PLCs can be interconnected to communicate with each other over a network. To coordinate the process and the PLC(s), a human-machine interface (a PC or a touch screen) is connected with the PLC so that the operators can manage the CIP conditions, including all the key parameters. The ability to change these key parameters should be restricted by a password. Many operator stations may be connected with the PLC(s), allowing operators from different locations in the food factory to control or monitor the CIP process. Further, a supervisory control and data acquisition (SCADA) system can be included to log and process data that provide the input for reports, analyses, statistics and diagnostic messages. All details of the completed steps in the cleaning cycle of a given process equipment may be shown on a colour graphic video display unit, so that operators and supervisors have the necessary information for each shift. Further each CIP cycle that was run is recorded so that it is fully traceable, even months later. Typical reports of a past CIP cycle(s) may include information such as (Rizoulières *et al.*, 2009):

- identification of the equipment cleaned;
- identification of the CIP station and ancillary equipment used to clean the process equipment;
- cleaning programme applied (i.e. sequence of cleaning steps);
- start and stop times for each step in the CIP process;
- historical trends of the key CIP parameters (given in a table or graph);
- main events and deviations (alarms) that occurred during the CIP cycle;
- amount of water and steam (the CIP station must be provided with flow meters), detergent and disinfectant used.

Automated CIP units make cleaning more effective and reduce cleaning costs through precise control of the variables (detergent concentration, temperature, etc.) associated with mechanized cleaning. Some units have as many as 200 different programmes. These provide: better recovery of

product, cleaning solution and/or rinse water recovery; significant reduction in detergent or disinfectant consumption; savings on energy; higher cleaning or rinsing efficiency. Automated systems have the potential to lower detergent chemical costs by 15–20%, and to reduce the cleaning cycle time by 10%.

### **10.12 Automated self-cleaning of CIP systems**

Periodically, in reuse CIP systems, the quality of the rinse waters and solutions stored in the rinse and detergent tanks respectively must be visually checked. The solutions and rinse waters in the tanks should be regularly sampled to monitor their microbiological quality and to determine the concentration of organic material and minerals present. If cleaning solutions become too concentrated with soil, they must be dumped and new cleaning solutions prepared. Nowadays, pollutants in used cleaning solutions can be removed using membrane technology.

Tanks and heat exchangers should be frequently inspected for the presence of mineral/organic deposits, and cleaned if necessary. For that purpose, the design and automation of the CIP station should allow self-cleaning of its tanks, piping, valves and instrumentation (e.g. the tanks of the CIP station must be fitted with their own spray balls). Certain valves are necessary to perform this self-cleaning operation automatically in a predetermined sequence. The tanks of the CIP station may be cleaned in a prescribed order with cleaning solutions temporarily stored in these tanks. Afterwards the solutions are returned to the previous tank or transferred to the next tank.

### **10.13 Future trends**

Irrespective of what a company manufactures, reducing production costs is the most important objective. It marks the difference between closure and success. The food industry is no exception. Cleaning and disinfection are essential parts of daily life in a food factory. However, they prohibit food producers from producing 24 hours a day. Therefore, every company aims to reduce the time spent on cleaning and disinfection. Reducing cleaning time starts with the process itself. If the food manufacturer operates the process for longer than the recommended processing times or if the production process is run in unsuitable conditions (e.g. too high temperatures), major fouling and more adherent deposits may form on equipment surfaces (such as the plate heat exchangers), increasing the time needed for cleaning. To reduce the time required for cleaning and disinfection, detergent manufacturers try to develop cleaning formulations that combine one or more steps in a normal cleaning cycle. A major research



objective of every supplier of cleaning agents is developing a cleaning formula that permit removal of organic and inorganic soil in one step, or that can clean and disinfect simultaneously (e.g. removal of inorganic deposits and simultaneous disinfection with peracetic acid). To facilitate the removal of heavy soil deposits, the use of detergent formulations based on enzymes has gained a lot of interest in the food industry. However, enzymes are currently still quickly inactivated at high temperatures, making development of more heat-resistant enzymes a major challenge. Problems with allergic reactions and cost also prohibit enzymes from becoming the new cleaning agents of the future.

In order to improve cleaning processes, the first steps in the direction of ultrasonic cleaning and other alternative methods have been taken. In several laboratories, mathematical tools such as computational fluid dynamics and mathematical modelling are used to better understand the effect of flow in cleaning piping and the impact of spray or jets on tank walls. These studies must aid food manufacturers in the localization of bottlenecks in their process installation which can impair suitable cleaning, or help tank cleaning equipment manufacturers to develop improved cleaning devices.

For expensive food products, new methods of recovery, such as the use of ice pigs, is becoming a new trend. Also, to reduce the cost of water and of wastewater treatments, maximum recovery of water and cleaning solutions is important. Membrane modules have been introduced as part of today's modern CIP installations, but more physical, chemical and heat resistant membranes (e.g. ceramic membranes) are needed. Also, improved instrumentation and new sensor technology (e.g. spectroscopic sensors) may assist in better separation of CIP solutions, hence lowering the consumption of water and chemicals and reducing waste volumes.

## 10.14 Acknowledgement

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# 11

## Hygienic practices for equipment maintenance

**F. Moerman, Catholic University of Leuven – KU Leuven, Belgium,  
J. T. Holah, Campden BRI, UK and P. Steenaard,  
European Hygienic Engineering & Design Group, The Netherlands**

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**Abstract:** Food processing equipment is susceptible to failure and deterioration in performance over time due to wear and tear. Where food manufacturers in the past resorted to inefficient ‘breakdown’ maintenance and repetitive repair, they now use predictive and preventive maintenance as a tool to detect and prevent premature failure. As part of preventive maintenance, the equipment’s overall condition and integrity, sources of food hazards, e.g. physical contaminants and microorganism harbourage sites, are assessed, frequently requiring the dismantling of equipment. Subsequent servicing often requires further break-in to the system, such that preventative maintenance may in itself become a food contamination risk. This chapter provides guidance to food manufacturers and maintenance operators in the application of appropriate hygiene procedures during the maintenance of food processing equipment and utilities, to ensure that equipment after reassembly will not compromise the product integrity when returned to service and for a predicted, future time interval.

**Key words:** maintenance, contamination, hygiene, food product, lubricant.

### 11.1 Introduction

Food processing equipment, like all industrial plant, is susceptible to failure through breakdown, deterioration in performance owing to wear and tear with time and to obsolescence due to improvement in technologies. Breakdowns can result in the contamination of foodstuffs via foreign bodies from broken parts and/or lubricating fluids from, for example broken bearings, and as such, should be prevented whenever possible via the application of preventive maintenance schedules. However, as preventive maintenance requires the dismantling, servicing and reassembly of equipment, this must be undertaken in a hygienic manner to ensure that

the preventive maintenance is not in itself a food contamination risk. Finally, maintenance operatives, by their personal hygiene and work activities around the factory site, are themselves a potential food safety risk when undertaking maintenance tasks. Training of maintenance operatives in all aspects of their job requirements is thus essential.

## **11.2 Scheduled maintenance**

### **11.2.1 Maintenance and repair: a necessary evil**

Machinery should be regularly checked with respect to its performance. Equipment maintenance checks should include an assessment of the equipment's overall condition and integrity (e.g. whether it is working properly), the sources of physical contaminants (e.g. damaged, lost or worn parts, rust, loose/flaking paint, broken parts such as needles and blades, loose parts on equipment prone to vibration, polymeric deposits, friction, fatigue, chemical reaction) and the potential microorganism harbourage sites (e.g. worn or frayed hoses, gaskets or belts, porous welds, product contact surfaces). Increase in noise, lubricant consumption, temperature rise or increased leakage is usually the consequence of failure of equipment and its components. Worn parts should be replaced as soon as practical, not only to ensure that production is maintained but also to prevent debris, worn or broken parts from entering the food product or contaminating the production line.

The operator must also ensure equipment used for critical measurements is calibrated, is uniquely identifiable and must be used within its design and capacity (e.g. accuracy, calibration range, conditions of use). Items requiring calibration could include thermometers, temperature recorders, scales, test weights, metal detectors, gas analysers, pressure or heat sensors, chemical assessment equipment, flow meters, etc.

### **11.2.2 Scheduled preventive maintenance**

Scheduled preventive maintenance should be preferred over inefficient 'breakdown' maintenance and repetitive repair for the following reasons (Jha, 2006):

- to prevent unscheduled down time;
- to maximize the performance of all processing and service equipment;
- to maintain and/or enhance the energy efficiency of the process and service equipment (consumption of less electricity, fuel, air power, etc.);
- to maintain and improve the product quality and appearance (reducing the risk for product recalls);
- to extend the useful life of the process equipment;
- to save on spare parts, lubricants, maintenance chemicals, maintenance tools, etc.

- to reduce or eliminate property hazards, such as fire;
- to enhance the safety of all food factory personnel;
- to schedule times for it when no food is being prepared, reducing the risk that food becomes contaminated

No longer does the maintenance department have the luxury of extended periods of available equipment downtime in order to carry out maintenance, instead the maintenance function is moving toward a more predictive approach. If the failure characteristics of the equipment are known, predictive maintenance can detect the failure well in advance and appropriate actions can be taken in a planned and organized manner. Predictive maintenance makes use of a group of emerging scientific technologies that can be employed to detect potential failures: vibration analysis, thermal imaging, ultrasonic measurement and oil analysis. The maintenance technicians should be skilled to use these diagnostic tools, and they must have detailed knowledge of the operating characteristics of the equipment to make the correct failure diagnosis. By means of a risk analysis, the manufacturer may define which parts of the system are critical, ensuring that the necessary treatment (to which interval, to which time point, and with which measures) is undertaken. That maintenance schedule should be frequently reviewed during the initial operating period of an installation to establish the optimum maintenance frequency (Liggan and Lyons, 2011).

Unscheduled down time and 'breakdown maintenance' (maintenance when it breaks) can be reduced by the following:

- Proper selection of the materials of construction. They shall be adequate to cope with the food product produced, the cleaning and detergent chemicals used, and the process and environmental conditions encountered in the food industry. Chemical, physical and thermal resistance of the materials of construction have an enormous impact on the reliability of equipment (components) and the frequency of maintenance and repair.
- Select and purchase the right type of equipment for any specific job. Equipment must have sufficient capacity. If a machine that is of low capacity is consistently being forced to run at high capacity, no amount of preventive maintenance will cure it!
- Equipment shall be appropriately designed within predefined tolerances of use and conform to the required specifications. Define for all equipment or its components the working parameters and their minimum and maximum values. If the maximum operating limits of the equipment (components) are lower than those of the system in which it is being fitted, or if malfunction of the equipment (components) could result in serious contamination, ensure that the system can handle these over-limit situations.
- Ensuring proper installation and assembly (e.g. bearings frequently fail due to misapplication, overloading and misalignment).

- Conducting an inspection programme of equipment after delivery.
- A short period of in-plant testing of the equipment to screen the entire population of equipment for leakage, to verify if all components function appropriately so as to ensure that they will fulfil their duty once brought in operation to produce food.
- Correct start-up and efficient maintenance turnaround.
- Avoiding mishandling.

### **11.2.3 Scheduled hygienic maintenance**

Preventive maintenance is primarily undertaken in a 'failsafe' mode such that equipment is unlikely to break down during production periods and thus create downtime and production losses. Replacement parts, however, may become a hygienic risk before they physically fail. For example, as seals in pipe couplings become worn or lose elasticity resulting from extensive heating and cooling cycles, they can become microbial harbourage sites before they physically fail and cause pipe leaks.

The hygienic performance of replacement parts may only be applicable to certain parts of the factory. For example, for ready-to-eat products or other products where microorganisms can lead to food safety or spoilage incidents in particular, hygienic performance may be relevant in equipment after any heat treatment processes. Preventive maintenance schedules should take account of the hygienic performance of replacement parts, therefore, as well as their likely failure performance.

Such hygienic performance may not be predictable and is likely to be different for all food manufacturing processes where product constituents, process conditions and cleaning and disinfection programmes may all influence the changing physical condition of the replacement part. Following plant installation and commissioning, replacement items can be examined at intervals, e.g. every 2–3 months and up until the predicted failsafe replacement time, to observe any signs of deterioration which could lead to a microbial hazard. For example, if a replacement part has a predicted failsafe life of 12 months, it may require changing after 9 months because it becomes a microbial harbourage risk.

## **11.3 Design, installation and working practices for improved hygiene during maintenance and repairs**

Proper design and installation of the processing equipment and utility services, along with common-sense measures create the appropriate conditions to keep up a sanitary process environment during maintenance and repairs (Moerman, 2011):

- Equipment should be of such a design that cleaning or maintenance of it does not introduce food safety hazards, e.g. consideration should be

given to eliminate or minimize the need for physical entry into the system. All equipment parts and components shall be readily and easily accessible for inspection, maintenance and troubleshooting. For that purpose, enough space and clearance should be provided around equipment, process and utility piping, equipment utility connections, etc.

- It is the general philosophy of GMP (good manufacturing practice) to relocate all process and utility services to a lower technical grade location. Mechanical, electrical, pneumatic, hydraulic and electronic components, together with distribution conduits, valves, pumps, pressure reducers, gas cylinders, vacuum sources, compressors, etc., should be isolated in a technical room or technical corridor adjacent to the production room. By relocating piping utilities, large volume heating, ventilation and air conditioning (HVAC) ducts, instruments, pumps and valves into a false ceiling above the process room or a technical corridor, the amount of available space for production activities will increase. Moreover, maintenance operations of utility piping and systems that are out of the process areas will be much easier (e.g., maintenance personnel can access the technical area without special gowning; walkable ceilings that are high enough to allow maintenance technicians to stand erect), and may occur without disruption of the cleanliness of the high-hygiene space below (Fig. 11.1).
- Ensure adequate lighting, particularly where detailed or intricate work is required. Lamps with higher light output may permit the factory staff to perform inspections of the food processing equipment and the process



**Fig. 11.1** By relocating piping utilities, large volume heating, ventilation and air conditioning (HVAC) ducts, instruments, pumps and valves in a technical corridor, maintenance may occur without disruption of the cleanliness of the high hygiene space below.

environment more easily and profoundly, enhancing the detection of grease, leaking oil, failures, maintenance residues. Sufficient lighting is also essential to inspect facilities for dirt, pests and spills, and to clean and maintain them in suitable order. Torches to light dark places with process equipment should be resistant against breakage.

- Maintenance practices should be consistent with GMP. It is especially the task of the maintenance managers and supervisors to implement and guarantee 'maintenance best practice' so that equipment is reliable and available by eliminating the sources of contamination that cause downtime, quality holds and lost profits.
- Common-sense measures (e.g. correct maintenance attitudes) will help to ensure that the production area and products are kept free from contamination by undesirable microorganisms, filth, debris or machine parts. It is the responsibility of the maintenance and quality assurance department to regularly conduct audits to verify if the maintenance staff or contractors have adopted the correct hygienic practices during maintenance operations in their food premises, in compliance with existing national or international guidance and legislation.

## **11.4 Purchase and acceptance of bought-in equipment, tools and lubricants**

### **11.4.1 Equipment**

No equipment, spare parts or tools, etc., should be brought directly into a food production area. They should ideally be held in an external workshop or storage area or, if this is not possible, within the goods-in area, so that they can be inspected.

New equipment, which has been specified by the food manufacturer, should be inspected to ensure that it is not damaged and meets specifications. This could include a visual inspection and, if appropriate, an assessment of the equipment's surface roughness using an appropriate stylus instrument.

Equipment should then be physically cleaned and decontaminated, though ideally this should have been undertaken prior to the equipment arriving at the factory. For new equipment, this may be to remove any production lubricants or construction material deposits, but for secondhand equipment this could include food deposits, including potential allergens. In extreme cases, one of the authors is aware that secondhand equipment introduced strains of *Listeria* and *Salmonella*, prevalent in their original factories, into their new home. Special care should be taken, therefore, before introducing equipment into areas where ready-to-eat foods are prepared. Once equipment has been brought into food production area and installed in its operational position, it should be cleaned and decontaminated again.



Equipment can then be assessed for its operational performance (if this is possible out of its intended point of installation) and an inspection made to ensure all parts are correctly installed and tightly fitted.

Before entrance into the factory, additional information can be gained as to how the equipment will be cleaned or maintained in practice. The sanitation manager can examine the equipment and begin to devise cleaning schedules. This might involve the cooperation of the maintenance team to help in planned dismantling and reassembly and the design of any parts trolley that may be required to store dismantled parts during cleaning. The maintenance team can also begin to plan potential maintenance schedules and secure the provision of any specialist tools and spare or replacement parts.

#### **11.4.2 Replacement parts**

All materials used for maintenance and repair shall be fit for the intended use and if they are in direct contact with food, must be constructed of materials that will not contribute a food safety risk. Indeed many food manufactures, particularly those subject to Global Food Safety Initiative (GFSI, <http://www.mygfsi.com/>) audits, request certificates of conformity or other evidence from the replacement parts manufacturer to confirm its suitability for use.

In the EU, EC Regulation No. 1935/2004 describes materials that are suitable for food contact. In the fullness of time, this regulation will develop guidance on 17 groups of materials to include: active and intelligent materials, adhesives, ceramics, cork, rubbers, glass, ion-exchange resins, metals and alloys, paper and board, plastics, printing inks, regenerated cellulose, silicones, textiles, varnishes and coatings, waxes, wood. To date there is legislation on five groups; Directives 78/142/EEC relating to vinyl chloride monomers, 84/500/EEC relating to ceramic articles, 2004/13/EC relating to the use of certain epoxy, 93/10/EEC relating to regenerated cellulose film and 2005/79/EC, amending 2002/72/EC, on plastic materials and articles intended to come into contact with food. Legislation is more established in the USA with respect to food contact materials and guidance is contained in the Food and Drug Administration (FDA) Code of Federal Regulations (CFR), Title 21, parts 174–186.

Further to the requirement for replacement parts intended for food contact to be of approved materials for such purpose, EC Regulation No. 1935/2004 requires that replacement parts must be traceable. This is to ensure that the food manufacturer is in a position to recall any food products manufactured on lines that have been fitted with replacement parts that are subsequently found to be a health risk. Replacement parts must therefore:

- be traceable to a supplier;
- be traceable when in storage at the food manufacturer's site;

- be traceable as to which piece of equipment or line into which they were installed;
- be suitably identified to facilitate such traceability.

Prior to acceptance, all replacement parts should be examined to ensure that they meet the appropriate specification and for damage and/or contamination. All non-conforming, damaged or contaminated parts should be rejected.

### 11.4.3 Lubricants

Within Europe, food processing machinery should be designed such that no ancillary substances (e.g. lubricants) can come into contact with foodstuffs (2006/16/EC). However, on occasion, some lubricants may inadvertently come into contact with foods or food contact surfaces and such lubricants should be food safe. 'Food-safe' means that these lubricants will not harm the consumer's health if they accidentally come into contact with foodstuffs and are consumed. Historically in the USA, the United States Department of Agriculture (USDA) approved lubricants if their ingredients were listed on the FDA CFR, Title 21, section 178.3570 lubricants. Lubricants with ingredients meeting this standard, which lists both approved ingredients and the quantity of that substance that is permissible in foodstuffs, were labelled H1 lubricants. The USDA's authorisation and inspection programme was suspended, however, in 1998. The National Sanitation Foundation (NSF) continued to register food grade lubricants on a commercial basis as H1 lubricants, and a list of approved products can be found on their website (<http://www.nsf.org/>). More recently, INS SERVICES (UK) Ltd have also offered this service ([www.Insservices.eu](http://www.Insservices.eu)). Alternatively, lubricants can be approved to ISO 21469:2006, which in addition to requiring lubricants to be formulated from non-toxic materials as listed by the FDA or the European Food Safety Authority (EFSA), also requires them not to affect the organoleptic qualities of the food or to pose additional health risks, such as supporting microbiological growth.

H1 registered lubricants are available in the following categories:

- bearing greases for low temperatures, ambient temperatures and high temperatures;
- chain lubes for low temperatures, ambient temperatures and high temperatures;
- gearbox fluids (enclosed and open);
- assembly and anti-seize compounds;
- hydraulic fluids;
- compressor oils;
- airline lubricants;
- penetrating fluids;
- can seamer lubricants;

- sugar dissolving solutions;
- release agents;
- general purpose sprays and lubricants.

As with all raw material, ingredient and service supplies into the food factory, lubricant manufacturers should be part of a Supplier Approval Scheme. The European Hygienic Engineering & Design Group (EHEDG) guideline document 23 (Steenard *et al.*, 2009) includes a number of critical points, together with suggestions for their management. Lubricant hygiene is described in the guideline as: all measures necessary to ensure the safety and wholesomeness of food-grade lubricants. These measures shall cover all stages during preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply to the customer:

- for H1 approved lubricants, only food safe materials can be used;
- manufactured hygienically;
- quality approval scheme;
- a batch registration system and a raw materials identification system are recommended;
- analyses can be used to check the purity of the raw materials. Stored raw materials must be systematically checked to ensure that they are not outdated.

All shipments should be delivered in clean containers suitable for the transportation and protection of their contents with respect to integrity and quality and in keeping with good commercial practices; they must be labelled properly. All packs should be sealed with tamper-evident seals fitted at the point of filling. Deliveries arriving without their seals intact must be rejected, as there is no longer a guarantee that the lubricants meet the requirements of a food safe product (Steenard *et al.*, 2009).

## **11.5 Maintenance, repair and lubrication according to the principles of hygienic design**

### **11.5.1 Maintenance and repair according to the principles of hygienic design**

Maintenance and repairs should occur according to the principles of proper hygienic design to ensure that safe food is produced once production is resumed. The following recommendations should be followed (Moerman and Degraer, 2003; Den Rustfri Stålindustris Kompetencecenter, 2006; Moerman, 2011):

- Equipment repairs are intended to be permanent and must be performed using proper materials. The construction materials used during maintenance and repair must be compatible with the food product or



**Fig. 11.2** In this part of the process equipment, mild steel plate is combined with stainless steel bolts, giving rise to galvanic corrosion between the stainless and mild steel components.

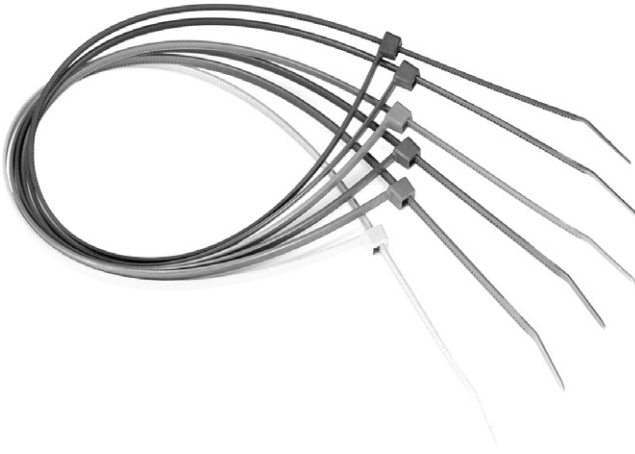
process aid they contain, and they shall not introduce contaminants that would present a risk to food safety. Piping and components should be constructed out of the same materials to prevent contact corrosion between dissimilar metals (Fig. 11.2).

- Work in black steel and stainless steel must always be kept separate. This also applies to storage.
- For optimum protection and cleanliness, the equipment supplier should deliver spare parts that are pre-packed in plastic in a clean environment, and in accordance with proper good maintenance practice and CMP they should be stored segregated from other non-stainless steel products. For example, in Fig. 11.3, the stainless steel equipment components are wrapped with plastic film, and their inlet and outlet connections are fitted with protective caps to protect them against corrosion and to prevent ingress of impurities, insects and small animals.
- Pipes, fittings, valves, components, etc., must be stored in dry, dust-free conditions, at a temperature corresponding to that of the mounting site. If this is not possible, the materials must be brought to the mounting site no later than 24 hours prior to the mounting so that they may achieve the temperature of the mounting room. This is to prevent condensation inside the pipes, which may cause welding defects and lead to the rejection of the welds.
- Precautions must be taken to prevent deformation of the stored materials through collision or insufficient support.
- The body and internal parts must be handled carefully to ensure that the machined surfaces are not damaged.
- Use as much as possible piping with the same internal and external diameter over the whole factory, in particular to avoid misalignment (missed coincidence between the axes of two coupled pipe components) prior to welding.
- Re-assemble piping and equipment components using a new seal, and check for leaks and re-tighten as necessary.



**Fig. 11.3** The stainless steel equipment components are wrapped with plastic film, and their inlet and outlet connections are fitted with protective caps to protect them against corrosion, dirt, pests, etc. during transport and storage (courtesy of Zhejiang Jugang Pipe Co, Ltd).

- All fastening devices should be secured firmly.
- If old insulation containing asbestos has to be removed, all precautions should be taken to avoid the spreading of asbestos fibres in the food processing environment. The food processing equipment and food product must not become contaminated by these asbestos fibres. During the removal of asbestos, maintenance technicians must use the necessary breathing protection, because asbestos fibers may cause long-term health problems such as lung and peritoneum mesothelioma.
- Preference should be given to styrofoam, foam glass or another rigid foam rather than fibrous materials that have already proven to be an excellent harbourage of dust, insects and rodents. Of course, asbestos must never be used. Afterwards, the insulation should be covered with cladding from aluminium or stainless steel sheets that have appropriate thickness and that resist tear and abrasion. The exterior of this insulation protection should be smooth, properly sealed to avoid ingress of dust and liquor, and with joints facing downwards.
- When a new cable has to be installed, it should not be supported from a previously installed cable. Such a practice leads to an uncleanable and hygienically unacceptable entangled cable bundle, where soil can build up. Electrical cables should be routed, and connections made, in such a manner as to create hygienically acceptable installations conforming to the pre-set hygiene class applicable for that area. The cables should be



**Fig. 11.4** If strips are the only option for temporary fixes, coloured plastic strips are available with metal content dispersed throughout the head and strap, so that even cut-off sections can be metal detected (courtesy of Detectamet Ltd.).

fastened individually at a distance (no less than 25 mm) from each other to allow proper cleaning.

- The use of temporary devices, such as tape, wire, string, etc., should be avoided. If strips are the only option, they should preferably be of a stainless steel type that can be detected by means of a metal detector. Alternatively, a plastic strip of a colour that is not omnipresent in the food product and food factory could be used. Nowadays, plastic strips are available with metal content dispersed throughout the head and strap, so that even cut-off sections can be metal detected (Fig. 11.4).
- Temporary fixes that may adversely impact the food safety or quality of a product must be dated, documented, and replaced in a timely manner by permanent repairs.
- Always determine the correct installation situation and direction of fluid flow. Install for maximum cleanability and drainability.
- Calibrated equipment that is non-conforming (i.e. broken, expired calibration period) must be identified as non-conforming, and not used for critical measurements until it is recalibrated, repaired or replaced.

### 11.5.2 Lubrication according to the principles of hygienic design

Food manufacturers should adopt a lubrication management system, comprising a factory survey to select the correct lubricants based on their technical efficacy and their harmfulness on incidental contact with food; lubrication frequency; lubrication monitoring, sampling and testing; record keeping for audit purposes and operative training in the use of lubricants.

EHEDG guideline document 23 (Steenard *et al.*, 2009) suggests that leakage of greases from bearings is a frequently occurring problem. Lubricants also often drip and splash from open lubricating points such as chains and open gears. Oil circulation systems, especially when the oil is under pressure from an oil pump, may allow small leaks to occur, which are difficult to detect. Hydraulic systems and hydraulically operated valves are other examples of potential sources of oil leaks. Leaks from oil-filled heat transfer systems are also difficult to detect. Leaks can also cause materials to corrode or to suffer electrochemical attack over a long period of time. Oil-coated machine surfaces such as chutes used to transport food, are also a source of contamination risk that has to be managed. Some food manufacturers use H1 lubricants only for critical lubricating points, with conventional lubricants being used for lubricating points that could not result in incidental product contact. Wherever possible, therefore, it is recommended that conventional lubricants are replaced by H1 lubricants, which considerably simplifies the management of critical lubricating points, as errors do not lead to the use of potentially toxic lubricants at these points. Moreover the number of lubricants can be considerably reduced.

The EHEDG guideline document 23 (Steenard *et al.*, 2009) describes sequential steps by means of which the maintenance department effectively can replace conventional lubricants by H1 lubricants. When changing the oils in reservoirs, it is recommended to drain the system, change the filters, flush the reservoir with a food grade product (flushing oil or original lubricant), check or change the filters again, fill from the reservoir with the correct food grade lubricant and take a sample for analysis. In the case of a grease application, it is recommended to check if the greases used are compatible. Clean the bearing out with a paraffinic oil or solvent, then fill the bearing(s) a third to half full with food grade grease and purge any grease lines with food grade grease. It is recommended to seek assistance from the lubricant supplier as required.

Lubricants may undergo changes during use and may degrade as they become older or are exposed to water and food materials. A lubricant that does not function properly may result in wear and tear, with the associated risk of product contamination by abraded particles. The presence of water in lubricants, in combination with an appropriate temperature, may lead to the multiplication of microbes, and one of the authors has been aware of the growth of pathogens including *Escherichia coli* and *Listeria monocytogenes* in lubricants giving rise to food product contamination. Some suppliers incorporate microbial growth inhibitors in their H1 lubricants. For some applications, such as microbial fermentations, these substances must be effective exclusively against the undesired microbes, so that fermentation is not impaired. It is advisable to carry out regular checks on lubricants to determine whether they are contaminated with microorganisms. Lubrication points where H1 lubricants may become



contaminated with beverages are also critical, as such contamination may encourage microbial growth.

When H1 and non-H1 lubricants are used within the factory, a system must ensure that no errors are made during packaging and labelling of storage and dispensing containers:

- H1 lubricants must be stored separately from toxic substances and dangerous materials. The storage of H1 lubricants in an area where conventional lubricants are also stored can lead to human errors and should be avoided. The use of dedicated transfer and storage containers for H1 lubricants is essential.
- Critical lubricating points must be labelled to reduce the risk of using the wrong lubricant. Text stickers or colour codes can be used for this purpose.
- To prevent degradation, stored lubricants must not be exposed to extreme temperatures.

The equipment lubrication process should also be undertaken in a hygienic manner with attention to the following:

- Use drip trays where possible in case lubrication points are situated above the product.
- Use the correct amount of lubricant. Adding too much oil to reservoirs and bearings may cause leaking, which could result in direct food product contamination. The same is true if excessive amounts of grease are applied (Fig. 11.5). Redundant lubricant and grease should be removed.



**Fig. 11.5** The use of excessive amounts of grease could result in direct food product contamination. The process equipment shown is clearly over-lubricated with a non-food grade grease (courtesy of John Butts, Land O’Frost).





**Fig. 11.6** Dedicated lubrication equipment should be used for lubrication and greasing. In high-hygiene areas, the use of a stainless steel grease gun and disposable funnels is recommended. Colour-coding of funnels and dispensing drums prevents cross contamination and misapplication of lubricants. That colour-coding also may assign lubrication tools to a specific hygiene area. Additionally, colour-coded labelling of all lubrication points will further prevent mixing of lubricants (e.g. food grade and non-food grade lubricants) (courtesy of Justrite Manufacturing Company, L.L.C.; courtesy of S & S Concepts Inc.; courtesy of KitchenWerks).

- To help prevent cross-contamination of different food grade lubricants it is recommended that dedicated lubrication equipment for greases and oils is used (Fig. 11.6).
- All containers/implements used for measuring, pouring or applying lubricants should not be used for anything else (e.g. labelled 'for chemical use only') and should be cleaned before use (Fig. 11.7).
- The equipment should be filled carefully with a clean can and a clean funnel, and a suitable cleaned tool should be used to apply grease.
- Any spills must be cleaned up and soiled wipes disposed of correctly. Dirty, greasy, oily hands should not be placed on any surface with which the product comes into contact.

After the lubrication maintenance has been completed, a paper or electronic job sheet should be completed and records kept for an appropriate period.

Regarding the storage of maintenance products:

- Maintenance products (oils, greases, lubricants, ammonia, glues, chemical products, etc.) should not be left in the food processing environment when maintenance operations have ceased (e.g. during the night, during weekends, during collective holidays).



**Fig. 11.7** The blue coloured brushes used for applying the lubricant are not suitable. They have turned the lubricant from white into blue. Further, the lubricant stored in the ‘in-use’ container has been cross-contaminated with other non-food grade lubricants, and has been exposed to the environment for too long, allowing dirt, pests, water, microorganisms, etc., to contaminate the lubricant. The container has also not been cleaned for a long time! (Steenard *et al.*, 2009; courtesy of Van Meeuwen Group).

- They shall be stored separately from food products in clearly labelled (identifying the maintenance compound) containers (e.g. bulk supply), that remain closed when not in use. These bulk containers must be stored in dedicated secure storage facilities, that must be kept clean and dry (Fig. 11.8).
- Maintenance compounds that are ‘in-use’ or for ‘immediate-use’ may be stored in processing and support areas, but only in quantities necessary for immediate use. When transferred from their original container (e.g. bulk supply) to the new container (e.g. ‘in-use’ or for ‘immediate use’), the latter must be labelled with the name of the maintenance compound.

## 11.6 Personal hygiene practices during maintenance operations in the food industry

Before the onset of maintenance and repair operations, all maintenance workers shall comply with the requirements for personal hygiene appropriate to the area where maintenance and repairs will be executed (Holah and Taylor, 2003; Aarnisalo *et al.*, 2006; Smith and Keeler, 2007; NZFSA, 2009; Stier, 2012). Please also see Chapter 12 on personal hygiene.



**Fig. 11.8** A correct storage facility helps to prevent contamination. Here, the food grade lubricants are stored off the floor and in clearly labelled containers (Steenard *et al.*, 2009), (courtesy of Van Meeuwen Group).

Because of their activities and movement around the food production site, maintenance operatives should view themselves as more of a hygiene risk than other food operatives and, at a minimum, should follow the same personal hygiene procedures as all other staff. In particular, maintenance staff are a foreign body risk and must remove all unsecured objects which could fall into the product, such as pens, pocket notebooks, small screw drivers, pencils behind the ear, non-attached ear plugs, nuts and bolts in shirt pocket, etc. Such items must be stored in the tool box or the carrier used to bring parts to the work site.

Particular attention should be paid to contractors, who may be unfamiliar with food hygiene requirements. Like all visitors to the factory they should complete visitor health check forms, but in addition, they should receive special inductions in food safety, particularly if they are entering food handling areas.

## **11.7 Hygienic maintenance and repair practices in the food industry**

### **11.7.1 Recommended hygiene practices to be taken before the onset of maintenance and repair operations**

The following measures and actions will create the appropriate hygienic conditions to execute maintenance and repair without compromising the safety of the food produced with that equipment when production resumes (Jha, 2006; Smith and Keeler, 2007; NZFSA, 2009, 2010):

- Some work such as drilling or welding will inevitably produce debris and dust. The area should be examined to assess the potential risk of contamination, and risk areas should be covered. Where possible, production operators should remove food processing equipment from the processing room before repairs are made. Coverings such as tarps or plastic sheeting (polyethylene or equivalent film) can be draped over equipment to reduce contamination as long as these items are clean and free from dirt or water.
- Maintenance should be done in a separate room outside the food processing area whenever possible.
- If entry into process equipment is required, a plastic cover film must be laid down on the bottom of the process equipment.
- Maintenance workers must necessarily use many tools in the production area. Where practical, maintenance tools should be dedicated for use in specific areas of their operation to avoid transfer of microorganisms in a hygienic room from its prior use in a less hygienic area. By dividing the production premises into visually segregated zones, where each zone has its own coloured set of cleaning and maintenance tools, hygiene can be improved and cross-contamination can be eliminated.
- Tools used for repairs and maintenance must not come in contact with, or compromise the hygienic status of, any product or packaging material. The maintenance tools must be free of rust, peeling paint, niches and threads; and without wooden handles or knurling soft rubber grips. They should be non-corrosive, easy to clean and inspect, with smooth finish and hard plastic grips, and with fitted heads for equipment longevity. They must be designed in a way that they cannot damage the process equipment. Today, stainless steel maintenance tools are available that are easy to clean and disinfect (Fig. 11.9).
- In certain conditions the use of non-metal tools is preferred over metal tools, especially if the latter can damage process equipment parts.
- Maintenance tools must be clean and used with care so that they cannot be left in the production equipment. Maintenance tools should be marked in a clearly visible fashion, to show that they are 'only used for maintenance operations'.
- Ordinary steel wool or steel brushes and scrappers should never be used on stainless steel surfaces as particles of steel may get embedded in stainless steel surfaces and rust.
- Debris from engineering workshops (such as swarf and other unwanted materials) must be prevented from entering processing or support areas. This is especially important where engineering workshops have access ways (e.g. doorways) that lead into processing or support areas. This may be achieved by keeping doors closed, the use of swarf mats, boot washes, etc.



(a)



(b)

**Fig. 11.9** (a) The maintenance tools shown suffer from corrosion, are painted (paint may peel off), contain niches and threads; have wooden handles or knurling soft rubber grips; or the tool heads may damage the stainless steel surfaces of equipment and components. (b) These maintenance tools are made of stainless steel (non-corrosive), are easy to clean and inspect, with a smooth finish and hard plastic grips, and have fitted heads for equipment longevity. If there is an electrical hazard risk, stainless steel tools must only be used if they have a hard plastic grip. A system of colour-coding allows the maintenance tools to be dedicated for use in a specific zone, such as a low- or high-hygiene area (courtesy of John Butts, Land O'Frost; courtesy of Steritool Inc.; courtesy of Detectamet Ltd).

- Tool boxes, receptacles, trolleys and parts should be assessed for their suitability for use in the intended environment. Where necessary they should be cleaned and disinfected before being taken into processing and/or support areas.

### **11.7.2 Recommended hygiene practices during maintenance and repair**

The following hygiene practices should be followed during maintenance and repair (Smith and Keeler, 2007; NZFSA, 2009, 2010):

- During maintenance operations, light sources used to provide the necessary light for proper maintenance and repair should not be placed above open process equipment, or the lamp should be housed in a shatter-resistant fixture to avoid any shattering of glass leading to broken fragments falling into that open processing equipment. Using a protective polytetrafluoroethylene (PTFE) coating maintains the integrity of the lamp in the event of breakage. Light sources used during maintenance operations should not contain mercury.
- Opening the distribution system will expose the system to particles from the outside environment. When altering the system, the contamination risk can be minimized by using strict specifications on how to conduct activities, such as cutting pipe work, and handling pipes and components before the actual installation. Precautions should be taken to prevent the distribution of any contamination residues or mechanical damage residues in the surroundings. Doors and windows should remain closed during maintenance operations, to prevent high-velocity air from entraining maintenance debris. These high-velocity air currents also may occur in the neighbourhood of exhaust openings and the air supply. However, natural or mechanical ventilation (at low air velocity) should be provided to minimize the likelihood of airborne contamination of food and to provide a safe working environment by effectively removing smoke, fumes, combustion gases, toxic gases, oil vapour, metal vapour, obnoxious odours, dust, etc. It is recommended to collect most of the maintenance debris at its source: vacuum cleaners should be applied to extract maintenance debris at the place where the maintenance takes place, drip pans should be used to collect oil, etc. But to maintain the interior of the process equipment and components free from any external contamination, the food producer also may protect the equipment openings. Overall, to diminish the risk for contamination of the food processing areas, maintenance activities should preferably be performed during shutdown periods (e.g. collective holiday).
- Equipment components subjected to maintenance, spare parts and tools should not be placed on the ground or walking surface (e.g. deck), but on a plastic pallet, in a receptacle, a box, a carrier or a trolley provided with a plastic cover. In the food processing area, no wooden pallets should be used to store new or replaced equipment components.

- Whenever parts and tools are stored in the production area, they should preferably be kept in rooms or lockers reserved for that use.
- Equipment components in service should be clearly indicated and placed in quarantine.
- To facilitate correct reassembly, disassembled equipment parts should be positioned in chronological order of disassembly. Wrong reassembly practice may cause damage to the machined surfaces of process equipment components.
- Take care not to lose nuts, bolts, etc., when removing them from machinery. Because small parts can easily be misplaced, loose bolts, nuts, screws, rivets, washers, etc., should be stored in maintenance receptacles.
- Bolts, nuts, screws, etc., of a lower alloy composition may not be used with stainless steel, because they may induce corrosion.
- Proper access for maintenance should be ensured e.g. by stepladders or mobile platforms (cherry pickers). This is to prevent, for example, maintenance personnel stepping on the cladding of insulated piping which could result in it becoming damaged. When the insulation is torn, it could become a sanitation problem (harbourage of dust, insects and rodents; absorption of moisture from air or spills may allow the growth of moulds). Damaged or wet insulation should be repaired or immediately replaced.
- Personnel must be trained and suitably skilled in the correct access, handling and use of approved maintenance compounds, or have access to documented directions. Documented directions must be followed, either at the point where the compound is used (i.e. on the container label), or on information data sheets available to the person using the compound. Processing areas or equipment contaminated by a maintenance compound must be corrected according to the maintenance compound's properties and its effect on the product's fitness for intended purpose.

### **11.7.3 Recommended hygiene practices after maintenance and repair**

After maintenance and repair operations, the following practices should be followed (Smith and Keeler, 2007; NZFSA, 2009, 2010):

- Maintenance tools or machinery must be removed or returned to storage without delay once maintenance or repair work is completed. Therefore, maintenance technicians must verify that all maintenance tools and components are removed after maintenance and repair to ensure nothing is left where it may enter the product or damage equipment. An inventory can be made of all tools prior to maintenance. If required for continuous use, tools must have a designated storage place and be maintained in a hygienic manner.



- It is good practice to 'count-in' all tools and replacement parts taken to a job and 'count-out' all tools and removed parts to ensure that everything is removed from the food processing area.
- Any part removed from equipment that is suspected of being microbiologically contaminated must immediately be sealed into a container or plastic bag to ensure that it does not 'drip' contamination around the food processing area.
- Appropriate waste removal and disposal procedures should be in place. Any maintenance waste and other refuse (e.g. packaging materials, broken components, failed parts, dirt, dust, spilled oil) must not be allowed to accumulate in production areas, but should be regularly removed to a suitable storage area and without delay.
- Damaged, decommissioned or idle equipment must be stored in an appropriate way to ensure it does not become a source of contaminants or harbours pests. Equipment that could be a source of contamination must be physically isolated from processing lines and product, or removed from processing areas. Nothing should be left in a food production facility that is not part of the production process. Damaged or decommissioned equipment that remains in processing areas must be clearly identified as such, to ensure that it is not used. De-commissioned equipment may be stored outdoors, but should be placed on a hard standing (e.g. concrete, sealed or paved area) and covered.
- If emergency repairs were required during production, any product that may have been left sitting for long periods of time or become contaminated during repairs should be disposed of to prevent any potential for poor quality or contamination of the final food product.
- Maintenance debris (e.g. abraded particles, swarf) may act as an abrasive that grinds off more particles from the pipe or equipment wall. Therefore, it is necessary to flush the system after maintenance and repairs.
- When it was necessary to 'break in' to the system for maintenance or inspection, procedures should be in place to ensure that equipment is clean and will not compromise product integrity when returned to service. Therefore, equipment should be thoroughly cleaned any time maintenance or repairs of any type are performed in a food processing facility. The equipment and area should be cleaned with solutions of detergents and disinfectants in the right concentration, then rinsed, and finally dried prior to resuming production.

## **11.8 Evaluation of the quality of maintenance work done and record keeping**

Before production resumes, the food manufacturer must evaluate if finished maintenance operations and repairs meet expectations with respect to



the quality of the maintenance and repairs. In this perspective, the following practices should be followed:

- Equipment must be subjected to a pre-operational check before processing recommences. Have all technical problems been solved and is the equipment operating correctly? Have maintenance and repairs been done in a way that the process equipment allows the production of safe food products once production resumes?
- Equipment operating under validated conditions must be revalidated if the repairs and maintenance activity may affect its validated status (e.g. replacing temperature probes /sensors in ovens/freezers).
- Maintenance records or job sheets (including when and how the defect/breakdown was repaired, who conducted the work, who has signed-off that it was completed and that appropriate equipment return-to-use procedures followed) should be completed. Comprehensive maintenance records will assist the operator to verify that the repairs and maintenance programme is working correctly.
- Irrespective of whether maintenance has been carried out in a workshop or within the food production environment, the equipment must be cleaned by the sanitation crew. The sanitation crew must also keep records to indicate the sanitation undertaken and any visual, ATP or microbiological sampling undertaken to verify cleanliness (see Chapter 16 on environmental sampling).
- Finally, the production department should sign off (e.g. on their daily record sheets) to indicate that they are content to accept the equipment back into production.

## 11.9 Conclusion

Food processing equipment is susceptible to failure and deterioration in performance over time, often requiring maintenance of and break-in to the system that may compromise the hygiene in the food factory. Maintenance operatives, by their personal hygiene and work activities around the factory site, are themselves a potential food safety risk when undertaking maintenance, repair and lubrication tasks. Guidance should be followed on how contamination can be avoided or reduced before, during and after lubrication, maintenance and repair. Maintenance workers must have knowledge of the principles of hygienic design, must be trained in good hygienic maintenance practices and should be familiar with maintenance record keeping and maintenance validation practices.

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# 12

## Personal hygiene in the food industry

**E. Margas, The University of Nottingham, UK and  
J. T. Holah, Campden BRI, UK**

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**Abstract:** There are a number of different mechanisms of product contamination caused by personnel, therefore a number of ways in which it can be reduced and controlled are recognized in this chapter. It is advised that food production facilities must have a comprehensive hygiene policy, appropriate facilities and clothing, effective training and assurance that sound employee and visitor hygiene practices are carried out. This chapter shows what good hygiene policy should contain, how to conduct effective training and what are the important aspects to consider during hand washing, hand drying and crossing the barrier between low- and high-risk areas. The importance of personal hygiene in food production and preparation facilities is emphasized by reference to associated legal requirements and food poisoning outbreaks caused by contamination from personnel.

**Key words:** personal hygiene, food processing, food hygiene, hand washing.

### 12.1 Introduction: definition of personal hygiene

People who work around open food may contaminate the food or surfaces that the food may come into contact with. Personnel are both reservoirs and vectors of microorganisms and can act as a source of microbial contamination to food products. The word hygiene usually refers to cleanliness and especially to any practice that leads to the absence or reduction of harmful infectious agents (Jumaa, 2005). This chapter deals with the mechanisms of product contamination caused by personnel and the ways in which it can be reduced and controlled by sound employee and visitor hygiene practices. The subject of personal hygiene is constantly evolving and, by its very nature of being 'personal', is influenced by a range of ethnic, cultural and personal views. Advice on personal hygiene is always available, both for food handlers and within the medical field, from government agencies, and technical reviews including Guzewich and

Ross (1999a, 1999b), Paulson (2000), Taylor and Holah (2000) and Smith (2009).

In the food industry the term 'personnel' is often taken to mean only operatives employed on the factory floor, but it should also include managers, engineers, contractors and visitors. Successful training and control measures for these operatives, who routinely handle food products, can be negated if other people passing through the processing area do not adhere to the same control measures. Personal hygiene should apply to everybody.

The different activities and the range of movement patterns that people undertake during their working day, and their perceptions and attitudes, mean that contamination from people can be complex and therefore difficult to identify and control. Direct contamination may arise by contact between the body, which acts as a reservoir of microorganisms, and the food product. The face, neck, hands and hair contain both a higher proportion of transient microorganisms and a higher general bacterial density (Troller, 1993). The reservoir of contaminating microorganisms on the body consists of both naturally occurring organisms and those acquired on the body through normal daily activities. Indirect contamination involves people acting as vectors, transferring contamination from one area or surface to another, for example transferring product soil and microorganisms on the sole of footwear to different parts of the food factory. This indirect mode also includes the movement of contamination into food processing areas if factory clothing is allowed to be worn in the canteen, toilets or the home.

### **12.1.1 Food poisoning outbreaks caused by food workers**

Many foodborne illness outbreaks have been caused by food workers' contact with food (Guzewich and Ross, 1999a; Olsen *et al.*, 2000; Greig *et al.*, 2007; Todd *et al.*, 2007a, 2007b). Guzewich and Ross (1999a) undertook a search of the published scientific literature for the period 1975–1998 which concluded that food workers, particularly those that were ill, could serve as the source of infection in food poisoning outbreaks and that hand contact with food was a mode of contamination.

The Committee for the Control of Foodborne Illness of the Association for Food Protection was tasked with collecting and evaluating data on food worker-associated disease outbreaks. In the first of a series of papers (Greig *et al.*, 2007), a total of 816 reports with 80 682 cases were collected from events that occurred from 1972 until the first quarter of 2006. Outbreaks were caused by 14 agents, including: norovirus or probable norovirus (338), *Salmonella enterica* (151), hepatitis A virus (84), *Staphylococcus aureus* (53), *Shigella* spp. (33), *Streptococcus* Lancefield groups A and G (17) and the parasites *Cyclospora*, *Giardia* and *Cryptosporidium* (23). Multiple foods and multi-component foods were identified most frequently with outbreaks, perhaps because of more frequent hand contact during preparation and serving.

In the second paper in the series (Todd *et al.*, 2007a) the Committee continued its analysis of the 816 identified outbreaks to examine morbidity and mortality and the settings where the outbreaks occurred. Overall, the hospitalization rate was low (1.4%), and deaths were rare (0.11% of the 80682 cases). An analysis of the settings for the food worker-related events showed that most of the outbreaks came from food service facilities (376 outbreaks [46.1%]), followed by catered events (126 outbreaks [15.45%]) and healthcare institutions (43 outbreaks [5.3%]). The single most frequent reported setting was restaurants, with 324 outbreaks and 16938 cases. Sixteen outbreaks occurred where primary produce was harvested and shipped from one country to another. Sometimes the presence of an infected worker preparing food was only one of several factors contributing to the outbreak.

The third publication (Todd *et al.*, 2007b) reviewed the role of food workers in the 816 outbreaks, and the factors contributing to the outbreaks, and described the different categories of worker involvement. All the outbreaks had worker involvement of some kind, and the majority of food workers were infected. The most frequently reported factor associated with the involvement of the infected worker was bare hand contact with the food followed by failure to properly wash hands, inadequate cleaning of processing or preparation equipment or utensils, cross-contamination of ready-to-eat foods by contaminated raw ingredients and (for bacterial pathogens) temperature abuse. The most frequent scenarios were (i) a single worker causing an outbreak by directly infecting patrons; (ii) an infected worker faecally contaminating foods that were then temperature abused, leading to an outbreak and (iii) multiple workers linked to an outbreak but with no clear initiating source.

In conclusion, the published literature confirms that food poisoning outbreaks may be caused by contamination from personnel and reinforces the need to ensure strict personnel hygiene procedures in the food industry.

### **12.1.2 European legal requirements**

European legislation specifies legal requirements for food handlers in Regulation (EC) 852/2004 on the hygiene of foodstuffs. The regulation states that:

- Staff handling foodstuffs must be in good health and undergo training on health risks.
- Appropriate facilities are to be available to maintain adequate personal hygiene (including facilities for the hygienic washing and drying of hands, hygienic sanitary arrangements and changing facilities).
- An adequate number of washbasins is to be available, suitably located and designated for cleaning hands. Washbasins for cleaning hands are to be provided with hot and cold running water, materials for cleaning hands

and hygienic drying. Where necessary, the facilities for washing food are to be separate from the hand-washing facility.

- Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.
- No person suffering from, or being a carrier of a disease likely to be transmitted through food or afflicted, for example, with infected wounds, skin infections, sores or diarrhoea is to be permitted to handle food or enter any food-handling area in any capacity if there is any likelihood of direct or indirect contamination. Any person so affected and employed in a food business and who is likely to come into contact with food is to report immediately the illness or symptoms, and if possible their causes, to the food business operator.

Food business operators are to ensure that:

- food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity;
- those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation or for the operation of relevant guides have received adequate training in the application of the HACCP principles; and
- there is compliance with any requirements of national law concerning training programmes for persons working in certain food sectors.

### **12.1.3 Microorganisms carried by personnel: resident and transient microflora**

The reservoir of microorganisms on and in the body can be divided into two broad categories: those found on the external surface, i.e. on the skin and hair, and in the nose, mouth, ears and eyes, and those found in the alimentary tract, which are excreted in the faeces. The skin microorganisms are the most important regarding the risk of cross-contamination, and can be further divided into two categories: transients and residents. Transient organisms are acquired in the process of normal everyday activities, e.g. every time the hands come into contact with a surface. In the food industry, microorganisms can be acquired from handling raw materials, processed foods, contaminated equipment and contaminated clothing, touching other body parts or poor toilet hygiene. If the hands have been handling raw materials of animal or plant origin then the transient organisms could include pathogens. Generally, transient organisms do not have sufficient residence time to multiply, and they are easy to remove by, for example, simple hand hygiene procedures. Localized lesions on the skin surface may harbour transients for a longer time period (sometimes becoming a temporary resident, e.g. *Staphylococcus aureus*) until the lesion has healed. Examples of transient organisms are Gram-negative bacteria such as *Salmonella* spp., *Escherichia coli*, *Pseudomonas aeruginosa* and *Klebsiella* spp.

The resident microorganisms live and multiply on the skin and constitute the normal microflora of the skin. The balance of residents is influenced by the presence of skin diseases or systemic illness. Generally, resident skin microorganisms are not food pathogens with the exception of *Staph. aureus*, which is often found on people as a temporary resident. Separation into the categories of residents and transients is useful but not always clear cut; for example, a transient organism may reside on the skin for long enough to be defined as a temporary resident.

Resident microflora are able to resist desiccation and the antibacterial properties of skin substances. The concentration of organisms varies over the body and on the hands, and is greatest on the fingertips and under the nails. The organisms reside as micro-colonies often attached to skin squames, which are constantly shed into the environment through normal everyday activities. The predominant resident skin organism is coagulase-negative *Staphylococcus epidermidis*, which is not normally a pathogen. The coagulase-positive organism *Staph. aureus* can sometimes be a temporary resident, usually in the nose, or where the skin is damaged or infected (McGinley *et al.*, 1988). In the moist areas of the skin, Gram-negative bacteria are more common and include *Acinetobacter* spp. and sometimes *Klebsiella* and *Enterobacter* (usually transient). Corynebacteria and propionic bacteria are other residents (Newsom, 1999). In general, resident bacteria are not usually pathogenic and therefore with some exceptions are not an issue when considering contamination of food from personnel.

Some viruses can also be transferred by food handlers to the food. The viruses cannot multiply in food; however, they can survive for long periods of time. Viruses can spread via contaminated hands or through the air via coughing or sneezing.

## 12.2 People as sources of contamination

Direct contamination involves the transfer of microorganisms from people to the food product by direct physical contact. The contamination may be a result of the transfer of microorganisms naturally harboured on or in the body acting as a reservoir or it may result from translocation of transient organisms. Translocation occurs by people acting as a vector, picking up pathogens from one activity (most likely by the hands), which are then transferred to another surface (which may be food) in a subsequent handling activity.

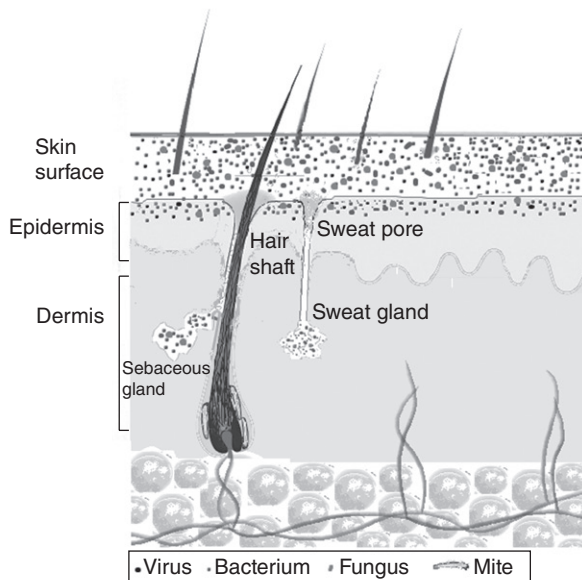
### 12.2.1 Gastrointestinal tract (GIT)

Faecal material contains very high numbers of bacteria; for example, Drasar (1974) presented information on bacterial populations from human faeces

sampled in the UK. The mean log 10 counts per gram of faeces were detailed as enterobacteria 7.9, enterococci 5.8, lactobacilli 6.5, clostridia 5.7 and *Bacteroides* 9.8. The gastrointestinal tract (GIT) is thus capable of sustaining considerable numbers of microorganisms and at times some of these organisms may be pathogens. Where workers have been ill with food poisoning, they will excrete the infective organism in the faeces for a period during the illness and for a time after symptoms cease. Such workers are a hazard to food safety. It is also possible for workers to carry infectious agents in their GIT without having any obvious symptoms; such persons are often termed carriers. Spread of contamination is either directly from the hands following poor toilet hygiene or indirectly as particles of faeces collected on the hairs in the anal region which are spread to clothing.

### 12.2.2 The skin

The surface of the skin is not flat; it is composed of flattened pavement cells (squames) composed mainly of keratin (Noble, 1981). There are various structures associated with the skin surface; these include hairs, sebaceous glands, and apocrine and eccrine sweat glands (see Fig. 12.1). The skin maintains itself by depositing perspiration, oil and dead cells on the outer surface. When these materials mix with environmental substances such as



**Fig. 12.1** Schematic of skin histology viewed in cross-section with microorganisms and skin appendages (Grice and Segre, 2011).



dust, dirt and grease, they form an ideal environment for bacterial growth (Noble and Pitcher, 1978). The epidermis (the outer layer of the skin) also contains cracks, crevices and hollows that can provide a favourable environment for microorganisms. The level of bacteria found on the skin ranges from approximately  $10^2$  to  $10^7$  colony forming units (cfu)/cm<sup>2</sup>. Both the number and type of bacteria vary on different parts of the body and the balance of the skin flora depends upon the presence of skin disease or systemic illness.

The hands are the major source of infection from transient and resident microorganisms. Horwood and Minch (1950) found that the number of organisms recovered from the hands ranged from  $1.5 \times 10^4$  to  $9.5 \times 10^7$  per hand. They also found that many of the organisms isolated from hands were derived from the food being handled and from discharges from the nose and mouth. The counts were similar for left and right hands, and day-to-day variation was small. Kerr *et al.* (1993) found that 12% of food workers carry *Listeria* spp. (7% were *L. monocytogenes*) on their hands whilst none in the control group (clerical workers) were positive for *Listeria* spp., indicating that hands are contaminated with organisms derived from handling foods.

The surface of the skin is continually replaced by the process of desquamation, leading to the squames at the surface being sloughed off and replaced with cells from the lower layers. Desquamation is the result of normal cell maturation, drying and the friction between clothes and the skin surface. The rate of loss of skin squames from the body varies according to the activity of the person, with sedentary activities resulting in the minimum loss of squames, whilst activities that cause greatest friction between the skin and clothes result in a greater loss of skin squames. During undressing it has been estimated that 500 000 squames become airborne, of which 5–10% may carry viable microorganisms (Noble, 1981), resulting in potential direct contamination of the food product. In addition, as skin secretions build up and the bacteria present continue to grow, the skin may become irritated. Food handlers may rub and scratch the area, thereby transferring bacteria to food from the skin in an indirect manner.

### 12.2.3 The hair

Hair is a significant potential source of contamination (Marriott, 1999) and hair density and oil secretions enhance the growth of microorganisms. Summers *et al.* (1965), cited by Woodroffe and Shaw (1974), examined the hair of hospital patients and staff. They found that 30% of individuals had *Staph. aureus* in their hair, 20% *E. coli* and 10% *Streptococcus* spp. Noble (1966), cited by Woodroffe and Shaw (1974), examined the hair of individuals with no hospital contact and those with skin complaints regularly attending hospital. He found 10% of the former group and 59% of the latter to have *Staph. aureus* present on their hair. The major route of direct infection from

hair is via hair loss and deposition into the product. For example, Hayes (1985) suggests that 100 hairs are lost each day. Hair can also act as an indirect transfer route, since, if hair is in poor hygienic condition and the scalp becomes itchy, microorganisms can be transferred to product via the hands after scratching.

#### 12.2.4 The mouth and nose

Large numbers of bacteria are present in the mouth. Bacterial colonization on teeth, referred to as dental plaque, contains in the order of  $10^{11}$  organisms per gram (Gibbons *et al.*, 1964). Saliva when secreted contains few bacteria, though as it bathes the teeth it becomes contaminated as a result of bacteria dislodging from the teeth surfaces and acquires up to  $10^9$  cfu/ml (Gibbons and Van Houte, 1975). Brushing teeth regularly prevents the build-up of bacterial plaque and reduces the degree of contamination that might be transmitted to a food product if an employee gets saliva on the hands or sneezes.

The nose and throat have a more limited microbial population than does the mouth. However, the nasal cavity is the most important reservoir of staphylococcal infection (Polledo *et al.*, 1985). Published accounts of nasal carriage of *Staph. aureus* range from less than 10% to more than 40% in the adult population (Noble, 1981). Occasionally, microorganisms penetrate the mucous membranes overlying the surfaces within the nose, sinuses, pharynx and oesophagus and establish themselves in the throat and respiratory tract. Staphylococci, streptococci and diphtheroids are frequently found in these areas, and are highly contagious.

Direct contamination from the mouth and nose to food products is via coughs and sneezes, or spitting. Photography using high-intensity short-duration flash has shown that during coughs and sneezing, droplets and strings of mucus may be ejected from the mouth and nostrils for a considerable distance (Lidwell, 1974). Indirect contamination is via touching or wiping the mouth or nose and then touching food, either through scratching or via eating and smoking.

#### 12.2.5 The ears and eyes

Various surveys have studied the microflora of the healthy ear (Singer *et al.*, 1952; Hardy *et al.*, 1954; Perry and Nichols, 1956; Moon *et al.*, 1965; Sommerville, 1966, cited by Noble, 1981), and found carriage of *Staph. aureus* of 8–22% and streptococci of 1–16% of subjects tested. The eye itself is normally free of bacteria but mild bacterial infections may develop. Bacteria can then be found on the eyelashes and at the indentation between the nose and eye. There is no obvious direct transfer from the eyes and ears to food product, though contamination could occur following scratching or rubbing these organs.

### **12.2.6 People as vectors of contamination**

Indirect contamination involves people acting as a vector, transferring contamination from one area or surface to another. Handling raw materials of animal and plant origin, cleaning utensils or waste materials, or touching the floor or drains and then subsequently handling food products or touching food contact surfaces without adequate hand washing, is likely to transfer microorganisms, potentially including pathogenic microorganisms. Clothing and footwear can become contaminated with pathogens during working activities and therefore have the potential to contaminate other surfaces when the operatives move around the factory.

## **12.3 Management practices for controlling contamination**

### **12.3.1 Management's responsibility**

To ensure that the company's personal hygiene policy can be fully met, the company should ensure that facilities are in place to both enable and encourage operatives to fulfil its requirements. This could include the following:

- Provision should be made for the storage (e.g. a refrigerator) and re-heating (e.g. a microwave and a kettle) of staff's own food if they wish to eat their own food and/or if a canteen service is not provided (some restrictions could be put in place due to allergen control).
- Suitable changing facilities for both sexes containing storage facilities for outside clothing and suitable toilet facilities, which do not open directly into food processing areas, should be provided. Factory clothing should be stored separately from outside clothing.
- Clean protective clothing should be provided daily. Following work activities, sufficient laundry bins for soiled clothing should be available.
- Hand wash facilities should be available, comprising non-hand-operated taps, liquid soap (in a cartridge form with an antibacterial agent to prevent bacterial growth in the soap) and appropriate hand drying facilities.
- Wherever possible, changing facilities should be sited to allow direct access to food processing areas without operatives having to traverse external areas.
- Alcohol dispensers may be provided for personnel to apply to hands just prior to work activities.
- Signs should be posted to notify employees of their entrance into food processing areas and for the need for hand washing.

Operatives are encouraged to follow basic hygiene procedures at home prior to arriving for work, and within the workplace they have to follow documented personal hygiene procedures. Such procedures cover the control of personal habits, the wearing of make-up and jewellery and hand

washing protocols. These procedures are established via thorough hygiene training as part of their induction process and reinforced by management supervision and audit. The food processor is responsible for providing a suitable range of protective clothing both to protect the operative from the processing environment and to cover the food handlers' body and so minimize the release of microorganisms from the body onto or near food operations. A laundry policy should also be in place to clean and maintain such protective clothing.

The control of indirect contamination routes is primarily concerned with recognizing that operatives can become contaminated in one processing area and can transfer this contamination when moving around the workplace. Sound hygiene policies concerning the physical structure and the operative changing practices should be in place at entrances to high-risk/high-hygiene or clean-room food production areas.

Management must establish appropriate procedures to ensure hygienic practices by employees. Supervisors and managers should set an example for employees by their own high levels of hygiene and good health while conveying the importance of these practices to the employees. In general, hygienic practices are more likely to be implemented if they are properly integrated into the organization's culture. If management takes good hygiene practices seriously, provides the time and resources needed and rewards good performance, employees will take their responsibilities more seriously.

### **12.3.2 Medical screening**

Effective control of contamination from personnel requires consideration of both direct and indirect modes. Control of the operatives begins with medical screening at the point of employment and is followed by daily assessment of employees' fitness to work. This is undertaken to ensure that employees do not work as food handlers when they are suffering from gastrointestinal and other illness that could increase their level of transmissible pathogenic organisms. Not paying staff when they are excluded from work due to being ill may lead to them working whilst sick, which may cause food safety problems.

Medical screening of food operatives is initially concerned with the requirement for medical certification of prospective new employees. In addition, it involves an ongoing awareness by operatives of their own health and the health of those around them (e.g. at home), from whom they themselves may become infected and thus subsequently compromise food safety. Advice on the assessment on suitability to work, in the UK, is given in the Department of Health Guideline *Food handlers: fitness to work* (Anon., 2009). The document does not recommend the use of stool testing prior to employment and suggests the use of pre-employment questionnaires, including, for example, the following questions:

1. At present or in the last seven days, are you suffering from
  - (a) Diarrhoea and/or vomiting?
  - (b) Stomach pain, nausea or fever?
2. At present, are you suffering from:
  - (a) Skin infections of the hands, arms or face, e.g. boils, styles, septic fingers, discharge from eye/ear/gums/mouth?
  - (b) Jaundice?
3. Do you suffer from:
  - (a) A recurring bowel disorder?
  - (b) Recurring infections of the skin, ear or throat?
4. Have you ever had typhoid or paratyphoid fever or are you known to be a carrier of *Salmonella* Typhi or Paratyphi?
5. Are you a carrier of any type of *Salmonella*?
6. In the last 21 days have you had contact with anyone, at home or abroad, who may have been suffering from typhoid or paratyphoid?
7. Have you visited any other countries in the last 6 weeks?

If the answer to any of the questions is yes, or if gastrointestinal illness develops during employment, the guideline provides details of requirements to be met before a food handler can start (or return to) work. Questionnaires of this nature should also be filled in by all visitors, auditors, customers, contractors, etc., who, whilst undertaking the purpose of their visit, may come into contact with the product directly or visit food processing areas. In some countries, whilst it is not illegal to ask such questions of employees, they may not have to answer them because of legislation concerning possible infringement of personal liberties.

Food handlers suffering from gastrointestinal infection, or who have been in close contact with someone who is ill, may contaminate food. The causative agents of gastrointestinal infection include *Salmonella* spp. (non-typhoid fever), *Salmonella* Typhi and *Salmonella* Paratyphi, *E. coli* O157:H7, *Campylobacter* spp., *Shigella* spp., *Vibrio* spp., *Bacillus* spp., *Yersinia* spp., *Clostridium perfringens*, *Staph. aureus*, viral gastroenteritis, *Entamoeba histolytica*, *Cryptosporidium parvum* and *Giardia lamblia*. Exclusion from work is also necessary when an employee is identified as a host for worms (threadworm and *Taenia solium*).

Once employment has started, any instance of potentially infectious diseases, including vomiting, stomach disorders, diarrhoea, skin conditions and discharge from the eyes, nose or ears, must be reported to the medical department, first aider or line supervisor. Managers must exclude these people from food handling duties and food handling areas. The length of the exclusion is usually 48 hours from when their symptoms stop. Different action may be required if an individual is diagnosed with a specific infection, and the cause has been confirmed as non-infective, or a person had only a single appearance of the symptom. Extra care should be taken over personal hygiene practices after return to work. Extra precautions may be required

if the operatives work involves handling foods for immune compromised consumers.

A record of the notification to management of the operative's illness and the subsequent action management has taken and the fitness of the operative to return to food handling duties, should be kept for purposes of demonstrating due diligence.

### 12.3.3 Training

Effective induction training and a programme of ongoing training are the best ways to educate and reinforce good personal hygiene practices. In one study of food handlers' attitudes, 62% admitted to sometimes not carrying out all food safety procedures on every occasion, with 6% admitting that they often did not (Clayton *et al.*, 2000). Lack of time was the most quoted reason for failure to implement agreed procedures. Griffith (2002) discusses models of food handler behaviour.

Employees should be provided with training in food handling and personal hygiene (Shapton and Shapton, 1991). Indeed, improved training has been advocated as a key way of improving hygienic practices in the food industry (Griffith *et al.*, 1995). Perhaps the most effective way to carry this out is to present all new employees with a comprehensive induction programme, then reinforce it through posters, and clear instructions in toilet blocks, changing rooms and hand washing facilities in the plant. Induction training can have a number of elements, depending on the nature of the product manufactured, but it could cover the following:

- Reading of the personal hygiene policy.
- Personal responsibility.
- Demonstration of an appropriate, validated hand hygiene procedure, followed by observation of an individual's compliance with the procedure.
- Visualisation of soiling level on the body and its reduction by good hand hygiene practices – the use of adenosine triphosphate (ATP) swabs before and after hand washing (Holah and Hall, 2003).
- Indications of areas of the hands frequently missed by hand washing – a number of companies now offer a kit combining a UV sensitive dye and a small, portable UV lamp. The dye is applied to the hands prior to hand washing and, following hand washing, the hands are placed under the UV lamp to indicate areas that have been 'missed' (see Fig. 12.2, Holah and Hall, 2003). Hands contaminated with the dye can also be used to touch other objects and the UV lamp then used to show the transfer of contamination from the hands to the touched objects.
- Evidence that wet hands translocate more microorganisms than dry hands – this usually takes the format of pressing the hands onto an agar plate, then wetting the hands and pressing them onto a second plate and observing any subsequent differences in microbial growth between 'dry' and 'wet' plates.



**Fig. 12.2** Visualization of contamination on the hands using a UV dye.

- Techniques that assess hand drying – during the induction-training period, operatives can be asked to wash their hands with coloured water, dry them as they would normally, and then place the hands on tissue paper. Detection of any coloration indicates poor drying. Alternatively, operatives' hands can be placed onto pre-weighed tissues after hand drying; the tissues are then re-weighed and the mass of water remaining calculated and compared to a target limit (Holah and Hall, 2003).
- Protective clothing requirements and use.
- Prevention of cross-contamination from raw materials to finished product areas.

After the training employees should know when to wash hands, how to wash hands, where to wash hands and how to disrobe and don factory clothing appropriately.

Regular group sessions, which can include videos, are also helpful (Sprenger, 1983). Additionally, there must be sufficient ongoing supervision of personal hygiene procedures in production departments to ensure that everyone complies with these procedures. Good hygiene practice should be part of any appraisal system of employees, supervisors and managers and violations of practices should be handled as disciplinary violations. Incentives for superior hygiene and sanitary practices should also be provided. Involving staff in developing and monitoring hygiene procedures is an effective way of winning commitment (Wallace, 2001).

Training should be provided in as many different languages as necessary and dated records of individuals' training should be kept and reviewed as appropriate.

Studies carried out by Widmer *et al.* (2007) evaluated the impact of training on the bacterial reduction achieved by using alcohol based hand rub. Training improved health care workers' compliance to 74% and



**Table 12.1** Food handlers and example of training requirements (JHIC, 1997)

Category	Activity	Training requirement
A	Handle low-risk or packed food only	Stages 1 (informal induction training) and 2 (further instructions within 4–8 weeks)
B	Prepare or handle open high-risk food	Stages 1, 2 and 3 (training beyond informal)
C	Food handlers with a supervisory role	Stages 1, 2 and 3 (training commensurate with a level 1 qualification)

increased log reduction from 1.4 log cfu/ hand before training to 2.2 log cfu/ hand after training.

A meta-analysis of food safety training on hand hygiene knowledge and attitudes among food handlers was performed by Soon *et al.* (2012). The results confirmed the efficacy of food safety training for increasing knowledge of and improving attitudes about good hand hygiene. Knowledge retention and behavioural changes among food handlers should be monitored, and refresher courses and targeted training should be designed and implemented.

Seaman and Eves (2005) reviewed the literature pertaining to the role of food hygiene training in a strategy to manage food safety. They describe an ‘Industry Guide to Good Hygiene Practice: Catering Guide’ (IGGHP) developed by the Joint Hospitality Industry Congress (JHIC, 1997). It suggests various levels of training depending upon the food handler’s competence, experience and career development; in summary the IGGHP suggests a simple framework for training commensurate with the employee’s duties. Examples of a training programme are given in Table 12.1.

## 12.4 Personal hygiene policy and practices for controlling contamination

### 12.4.1 Personal hygiene practices

The number of microorganisms arising from the skin and within the body of food operatives prior to commencing work, and therefore the potential risk the operatives present to the food product, are controlled by high standards of personal hygiene, including the following:

- having regular baths/showers;
- washing hair frequently;
- keeping fingernails short and clean;
- avoiding habits such as biting nails and ‘picking or scratching’ the nose and ears.



It is a legal requirement for every person working in food handling areas to maintain a high degree of personal cleanliness and wear suitable protective clothing.

Employees with one hand or a surrogate prosthetic device for hands and arms should also follow the hand washing procedures. Suitable devices are available which are attachable to a sink. These devices enable a one-handed employee to generate the necessary friction to achieve the intent of this requirement (FDA Food Code, 2009).

#### **12.4.2 Personal hygiene policy**

On arrival at their place of work, all operatives, visitors, contractors, etc., will be expected to abide by the company's personal hygiene policy. In many companies this document is an essential part of the company's induction training programme and operatives are often asked to sign a record to acknowledge that they have read and understood the policy and agree to abide by it.

The personal hygiene policy is usually a comprehensive document, though the sections that operatives need to be familiar with are usually more readily comprehensible, often in a number of languages and backed up by figures and posters as appropriate. The policy will include information such as the location and types of hand wash facilities, hand hygiene products used, hand hygiene procedures for employees, instructions for when to wash hands (including information on gloves), procedures for monitoring hand hygiene, procedures for the identification and control of dermatitis, training programmes and records, and details and frequency of hygiene audits.

The factory hygiene policy is often shortened to a number of key points and is posted around the factory and at reception as a quick reminder. It could typically include the following:

- *Protective clothing, footwear and headgear* issued by the company must be worn and must be changed regularly. When considered appropriate by management, a fine hairnet must be worn in addition to the protective headgear provided. Hair clips and grips should not be worn.
- *Protective clothing* must not be worn out of food production areas and must be kept in good condition.
- *Beards* must be kept short and trimmed and a protective cover worn when considered appropriate by management.
- *Nail varnish, false nails and make-up* must not be worn in production areas. Strong aftershave or perfumes must not be worn.
- *False eyelashes, wrist watches and jewellery* (except wedding rings, or the national equivalent, and sleeper earrings) must not be worn. Studs and earrings, if worn, should be covered in appropriate dressings.
- *Hands* must be washed regularly and kept clean at all times.

- *Personal items* including any medications must not be taken into production areas (handbags, shopping bags, mobile phones, etc., must be left in the lockers provided).
- *Food and drink* must not be taken into or consumed in areas other than the rest areas and the staff canteen/restaurant.
- *Sweets and chewing gum* must not be consumed in production areas.
- *Smoking or taking snuff* is forbidden in food production, warehouse and distribution areas. Smoking is only allowed in specific 'smoking areas' outside where staff can smoke before they wash their hands and return to work.
- *Spitting* is forbidden in all areas on the site.
- *Superficial injuries* (e.g. cuts, grazes, boils, sores and skin infections) must be reported to the medical department or the first aider on duty via the line supervisor and clearance obtained before the operative can enter production areas.
- *Dressings* must be waterproof, suitably coloured to differentiate them from product and contain a metal strip as approved by the medical department.
- *Infectious diseases* (including stomach disorders, diarrhoea, skin conditions and discharge from eyes, nose or ears) must be reported to the medical department or first aider on duty via the line supervisor. This also applies to staff returning from foreign travel where there has been a risk of infection.
- *All staff must report to the medical department when returning from both certified and uncertified sickness.*

The best personal hygiene policies are 'self-policing'. In this case operatives and managers tell each other if clothing is not worn properly or someone has spotted an operative touching their face and they need to rewash their hands. Such a practice can be very effective, especially when everyone is involved, including managers, visitors and engineers.

### **12.4.3 Factory clothing and footwear**

The wearing of the operative's own clothing for food processing operations is generally not permitted and the company usually supplies a range of protective clothing. Protective factory clothing is worn for two reasons, and it is important that the induction training programme reflects this. Personal protective equipment (PPE), which includes gloves, safety spectacles, ear defenders, aprons, overalls and footwear with non-slip soles and metal toe caps, is worn to protect the operator from the food processing environment (cold, water, food products, etc.) and specific safety hazards as appropriate (e.g. detergents and disinfectants). The second purpose of protective clothing is to protect the food from microorganisms released from the body. Protective clothing of this type includes hairnets, hats, masks, beard snoods,

overalls, coats, gloves, wrist and forearm sleeves, trousers and footwear. Consequently, the type of material used and the design of protective clothing will depend upon its prime function.

Factory clothing should be hygienically designed so that it does not shed foreign bodies directly (e.g. buttons or lint) or indirectly (e.g. having outside pockets from which objects can fall out and into the product). The clothing is often of different colours to delineate either operatives working in different risk areas or specific categories of people, e.g. engineers, cleaning staff, first aiders and management.

The frequency of clothing change and the degree of decontamination during laundering are dependent upon the type of food being produced. Clothing may be laundered in-house or can be undertaken by external contractors. Clothing laundered by external contractors, however, must be laundered separately from clothing from other industries. Changing of clothing daily is the preferred option as it is often easier to manage, preventing each operative having to make a decision as to whether his or her clothing needs changing. Traditional washing programmes are acceptable for most clothing (i.e. where visual cleanliness is the goal) but high-risk factory clothing requires greater standards of laundry sufficient to reduce the microbial load. This is usually achieved by higher laundry process temperatures such that the clothing receives a pasteurization treatment. Some laundries now operate with similar low-/high-risk principles as the food industry. Dirty clothing enters the laundry in the low-risk side and passes through the process of washing and disinfection to come out at the high-risk exit for drying, steaming and packaging.

Footwear is designed and worn for a number of reasons, including protection of the operative's lower legs and feet, as an aid to reduce slips and trips and to provide a degree of comfort and support when potentially standing at the production line for extended time periods. A range of footwear types can be worn to fulfil these requirements, from clogs to Wellington boots, but in all instances footwear must be designed so that their upper surfaces are washable and their soles are easily cleaned to remove debris.

#### **12.4.4 Hand hygiene**

Perhaps the most critical aspect of the reduction of the contamination risk from people is through hand washing. Hand washing and disinfection were reviewed by Reybrouck (1986) who defined the different terms involved and discussed the efficacy of various systems. The purpose of hand washing is to remove superficial desquamated skin squames, sweat, sebaceous secretions and associated transient bacteria as well as any organic material adhered to the hands acquired from normal activities. The immediate (transient removal) antimicrobial effects depend upon the types and amount of washing product, the time spent washing the hands, and the mechanical

pressure and friction employed. The persistent effects (resident removal) depend upon the topical and microbial product efficacy (Paulson, 1996). Hand hygiene procedures should not damage the skin. Damaged skin can be more heavily colonized with pathogenic microorganisms and it is therefore possible that excessive hand washing with soap may result in damaged skin and an increase in the number of flora over time.

Good hand hygiene encompasses the following:

- Undertaking hand hygiene at appropriate times.
- Undertaking hand hygiene only in designated hand washing sinks.
- Keeping nails short to make hand washing easier.
- Using a liquid soap (in a cartridge system) with an antibacterial agent to prevent microbial growth in the soap.
- Covering all the areas of the hands following the six-point hand washing sequence as described by Ayliffe *et al.* (1978) which is now incorporated in more detailed instructions (see Fig. 12.3).
- Thoroughly drying hands with paper towels or warm air hand drier.
- Finishing with an alcohol rub.

Appropriate times for the washing of hands are after any activities that could contaminate the hands with pathogens and include the following:

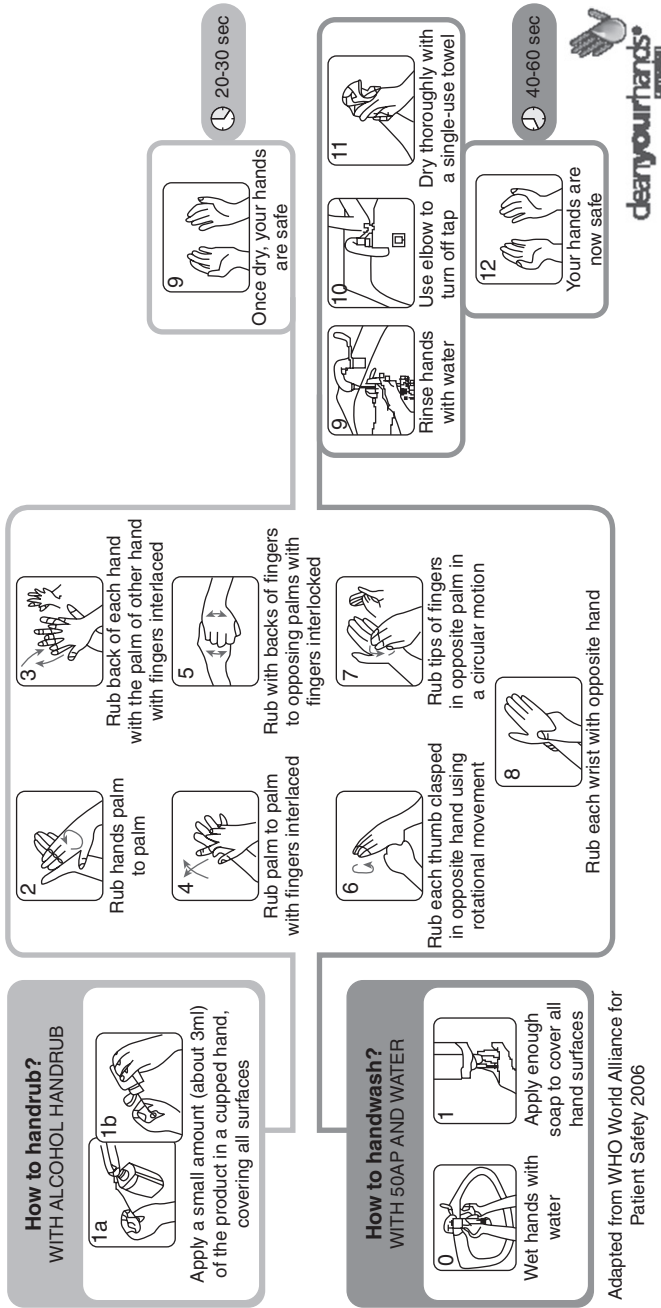
- visiting the toilet;
- changing a dressing or touching open wounds;
- contact with other people's skin, faeces or vomit;
- touching animals/pets;
- breaks;
- handling raw food;
- handling waste;
- blowing the nose and/or touching body parts;
- carrying out cleaning duties;
- removing gloves;
- handling non-food-contact surfaces, e.g. machine adjustment, power switches;
- working a shift.

In addition, hands should always be washed before the following activities:

- entering food handling areas;
- changing into high-risk clothing;
- putting on gloves.

Hand washing with both soap and water, which act as emulsifying agents to solubilize grease and oils on the hands, will remove transient bacteria. Increased friction through rubbing the hands together or by using a scrubbing brush reduces the number of both transient and resident bacteria. A cleaning compound will remove more transient bacteria, with subsequent destruction by a disinfectant. Standard soap consists of esterified fatty acids with sodium hydroxide or potassium hydroxide. Soap preparation

## HAND CLEANING TECHNIQUES



**Fig. 12.3** Standard NHS hand washing protocol, incorporating the six actions (steps 2–7) originally described by Ayliffe *et al.* (1978).

includes bars, liquids, foams and gels. The temperature of the wash water, however, is not thought to be important in influencing microbial removal (Michaels *et al.*, 2002) and wash water should ideally be warm to encourage operatives to wash their hands frequently (too cold discourages hand washing, too hot may cause discomfort). Warm water is also more effective than cold water when removing fatty soils; also an adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. The 2009 FDA Food Code (2009) specifies a minimum hand washing temperature of 38°C.

A suggested, comprehensive sequence for effective hand washing, modified from Marriott (1999), is described below:

- Wet hands.
- Apply soap.
- Rub hands to spread soap over hands up to wrists.
- Wash hands using the six-point hand washing sequence as described by Ayliffe *et al.* (1978). This is illustrated schematically in Fig. 12.3 with additional steps incorporated into the original sequence. All parts of the hands and wrists should be rubbed, with each step consisting of five strokes forward and backward.
- Brush nails and other areas where dirt may be difficult to dislodge (using a clean nail brush).
- Rinse hands.
- Rub hands to check whether all soap lather has been removed.
- Rinse hands again.
- Dry.

This simple hand wash has been shown to be effective at removing microorganisms from artificially contaminated hands, and reductions of between 2 and 3 log orders are typical in the scientific literature (Lowbury *et al.*, 1964; Mittermayer and Rotter, 1975; Ayliffe *et al.*, 1978; Paulson, 1994).

#### *Antiseptic hand washing*

Antiseptic hand washing can be defined as washing hands with water and soap or another detergent containing an antiseptic agent (Larson *et al.*, 1998). Sanitising antimicrobial agents exert a continuous antagonistic action on emerging microbes and enhance the effectiveness of ordinary hand soap at the time of application. Agents for hand disinfection must not be toxic, nor taint the food product, and should have a range of antimicrobial activity. Alcohol (70%) is the most widely used disinfectant in the food industry and is effective for rapid killing of residual transient microorganisms. Other agents such as hexachlorophene, chlorhexidine, quaternary ammonium compounds and iodophors may be used for activity against resident organisms such as *Staph. aureus*. The overall efficacy of an antimicrobial hand soap (other than alcohol-based products) depends on continuous use throughout the day. However, a compromise may have to be found between

efficacy and health and safety, as the frequency of hand washing in the food industry means that dermatitis may be a problem with some of these agents.

#### *Mechanized hand washers*

Mechanized hand washers may be useful in ensuring that hand washing is done thoroughly and frequently. In some cases such equipment has increased the frequency of hand washing as much as threefold (Marriott, 1999). In one example, jets spray a mixture of antimicrobial cleansing solution and water on the hands, followed by a potable water rinse. The 10-second, massage-like cycle has been clinically proven to be 60% more effective at removing pathogenic bacteria from the hands than the average manual hand washing (Anon., 1997). This process can accomplish hand washing with only one-third of the amount of water used in most manual hand washing methods.

#### *Hand rubbing*

In 2002, new guidelines for hand hygiene in health care settings were published in the USA by the international group from the Centers for Disease Control and Prevention (Boyce and Pittet, 2002). In general, the hands should be either rubbed with alcohol (the standard procedure) or washed with soap (if visibly soiled), but both procedures should not be used at the same time. In contrast to hand washing, the objective of hand rubbing is more effective and rapid reduction of skin flora by killing, not mechanically removing microorganisms. The technique usually consists of rubbing alcohol onto both hands until it completely evaporates, usually requiring 15 to 30 seconds. Most dispensers usually deliver 1.5–2.0 ml of alcohol per application; two applications are usually necessary to completely cover the hands.

The antimicrobial activity of alcohol is based on protein denaturation. For hand rubs, ethanol, isopropanol and/or *n*-propanol are used. Alcohol concentrations of 60–95% (vol/vol) kill 3.4–5.8 log cfu in 30 seconds, with higher concentrations heaving better antibacterial activity (Rotter, 1999). However, concentrations greater than 95% are less potent because water is essential for protein denaturation. The presence of organic material diminishes the antibacterial activity of alcohols by 0.2–0.7 log cfu. Alcohol solutions have poor activity against bacterial spores; therefore supplementation with 1% hydrogen peroxide may render alcohol sporicidal. Alcohol rubs are effective against some viruses, but not norovirus, particularly at higher alcohol concentrations (70–80%).

Antibacterial hand gels are often used after hand washing or during food handling activities. However, they only work properly on hands that are clean and free of soil and grease; products which do not contain moisturizers may enhance skin damage. Alcohol solutions lack persistent activity on resident skin flora and the addition of disinfectants (chlorhexidine, quaternary ammonium compounds, triclosan or octenidine) may delay the regrowth of bacteria. The use of alcohol immediately before or after hand

washing with soap and water is not recommended because it may cause dermatitis. Trampuz and Widmer (2004) studied the benefits of using a hand-rub procedure over a hand washing procedure. They found the following:

- Time required for the alcohol hand rub technique (15 to 30 seconds) is shorter than time required for hand washing (at least 1 to 2 minutes, including walking to the sink).
- Washed hands can become recontaminated by splashes from taps and sinks, where contamination of alcohol-based solutions has not been reported.
- There is a limited accessibility of hand washing stations, where as alcohol dispensers could be placed anywhere.
- Adverse effect on skin is rare when using hand washing and very rare when using alcohol-based hand rubs.
- Alcohol-based rubs can be flammable; however, there have not been many accidents reported regarding involving hand rubs.

#### *Alcohol wipes*

The use of alcohol wipes in the food industry has become more widespread, including for hand hygiene. Work by Taylor *et al.* (2000) has shown that cleaning artificially contaminated hands with non-alcoholic wipes reduced the microbial level by 2.2 log orders and with alcoholic wipes by 3.1 log orders. Both these results were broadly similar to those obtained for hand washing and hand rubs respectively. It may be a practical alternative, therefore, to use alcoholic wipes at a 'local' level on the production line, such that operatives needing to decontaminate their hands can use a wipe rather than having to keep returning to the hand wash basins. In addition, hand wipes can be useful for operatives in the food chain who do not currently have hand wash facilities, such as warehouse operatives and vehicle drivers.

#### *Hand drying*

Hand drying is at least as important as hand washing in preventing the translocation of microorganisms from the hands to the food product. Patrick *et al.* (1997) have also described the importance of water droplets in microorganism translocation and recommend that good hand drying is crucial in reducing translocation in clinical and public health sectors. Ballistic water generation and spread by any hand drying technique used should be considered, as contamination of food-contact or other hygiene-critical surfaces with water may transfer microorganisms and/or subsequently encourage microbial growth.

Drying of hands must be undertaken in a thorough manner. Warm air hand driers, air knife systems and single-use textile and paper towels are the preferred methods of choice, although some paper/textile reels that



automatically advance between dries could also be acceptable. Towels that are re-used by each operative should not be used. Warm air dryers have been shown to be as effective as paper towels with respect to the number of bacteria recovered from hands after washing and drying. In addition there is no evidence to show that warm air dryers contaminate the air; in fact it has been demonstrated that airborne microbial populations are reduced as they pass through the warm air dryer (Taylor *et al.*, 2000). Studies conducted by Snelling *et al.* (2011) compared an air knife dryer with warm air dryers with regard to bacterial transfer from hands after drying. For a drying time of 10s, the hands dried using the air knife had no moisture present, therefore this method led to significantly less bacterial transfer from hands.

The choice, therefore, between paper towels, air knife dryers or warm air dryers is based upon circumstance. Warm air dryers take longer to dry hands and for all electric dryers, sufficient units are required for the number of personnel needing to use them at the same time. Air knife dryers are faster but can spread the water droplets up to 2.5m to the sides. Paper towels may become a foreign body hazard to the food product and present a waste disposal problem, requiring good management to ensure that both towel dispenser and bins are filled and emptied effectively. The quality of paper towels is also important; poor quality towels may damage skin by abrasion and ineffective drying.

Hands should be dry prior to food handling activities. It is recommended that all hand drying be conducted in an area segregated from the food production area, ideally in a separate room so as to minimize any risk of microbial or physical contamination of the product. The use of alcohol-based hand gel following hand drying may help to further reduce hand moisture levels and thus minimize contamination transfer.

### *Gloves*

Following handwashing and drying, the benefits of wearing or not wearing gloves for food handling are still under debate. Initially, gloves present a clean contact surface, and bacteria that are sequestered on and in the skin are not permitted to enter foods as long as the gloves are not torn or breached in some way. However, the skin beneath the gloves is occluded, and heavily contaminated perspiration builds up rapidly between the internal surface of the glove and skin. If this contamination contacts the food through a breach in the glove barrier, the food will receive a much higher inoculation of microorganisms than would have been transferred from the bare hand. In addition, the gloves themselves soon become contaminated and a hygiene risk unless they are frequently washed or replaced. Gloves also tend to promote complacency that is not conducive to good hygiene. If gloves are used, for example to protect the hands, or to prevent skin irritation or dermatitis from frequent washing, thorough washing of hands needs to be carried out both before and after putting on

gloves. The gloves need to be changed approximately every two hours (this usually corresponds to break times), whenever they are damaged or holed and when they are in contact with potentially contaminated surfaces. There are no microbiological or physical standards for gloves, and their sterility, physical integrity and chemical content (with respect to food taints) should be carefully specified to the glove manufacturer. When selecting gloves, management should bear in mind that some people are allergic to latex, or can develop an allergy from regular contact. Alternative glove materials include nitrile, vinyl, rubber and plastic.

## 12.5 Control of indirect contamination from people

Control of indirect contamination from people, where people become a vector for moving contamination from one area of the plant to an area of higher hygiene control, is a particular problem for certain sectors of the food industry such as ready-to-eat foods. This is because these types of processing operations recognize different hygiene zones, or risk areas, divisions between which are usually associated with a product heat treatment or decontamination step. Within the higher-risk area, the food is often not further processed before eating and it is therefore essential that this area remains free of pathogens. It is essential, therefore, that staff moving from a lower-risk zone, in which pathogens may be present, into the higher-risk zone, do so in such a manner that any contamination on their bodies is controlled at the point of transfer.

In this respect, the three key sources of contamination that have to be controlled are the operative's footwear, clothing and hands. Footwear, clothing and hands may become contaminated in the low-risk area by direct contact with the external environment, raw materials, food wastes, etc., whilst hands can be further contaminated in the process of removing low-risk clothing and footwear at the low-risk/high-risk barrier. No single barrier can be completely effective for preventing contamination of food during production. Multiple hurdles are required to reduce the likelihood of pathogens reaching the consumer. Consequently the use of combination of physical and chemical barriers, and in some cases complete avoidance of an activity, is most effective (Todd *et al.*, 2010).

### 12.5.1 Low-risk/high-risk barrier

Footwear is a potential vehicle for moving pathogens from one risk area of a factory to another and its control is simple. At the low-/high-risk barrier, footwear can be either 'captive' to, i.e. remains in, the high-risk area (preferred) or overshoes or 'booties' can be donned over the low-risk footwear (less preferred as the overshoe material may be prone to tearing). Studies by Taylor *et al.* (2000) have shown that, under factory conditions,

when footwear was soiled with both food debris and microorganisms, foot baths and bootwashers were ineffective at removing all organic soil and thus could not remove and/or inactivate all microorganisms. In some cases, because the footbaths and bootwashers had become contaminated, the level of microorganisms was greater after bootwashing than before. In addition, footwear can transport contamination significant distances, with dry contamination being transferred up to 35 m on dry floors and over 47 m on wet floors, and wet contamination being transferred up to 24 m on dry and over 35 m on wet floors (Taylor *et al.*, 2000). Bootwashers also have the potential to create microbial aerosols that can transfer contamination from the footwear to the operative's clothing. Therefore, bootwashers and/or footbaths do not form effective pathogen barriers between low- and high-risk areas. For captive footwear, and when a risk assessment has shown that footwear should be frequently washed to prevent slip and trip hazards, the use of boot wash facilities at the entrance to a high-risk area is acceptable where this is managed and validated to effectively prevent the introduction of pathogens. The site shall undertake a risk assessment to identify the suitability of the boot wash facilities and controls to manage the effective sanitation of footwear. The controls shall be validated by microbiological swabbing of footwear, floors and the drains in the high-risk area, to demonstrate the absence of pathogens.

For such controls to be effective it would be expected that this includes the following:

- The footwear shall be company issued and of a design that is easily cleaned (i.e. smooth upper surfaces, cleats on soles shall be sufficiently spaced so as not to trap dirt which may not easily be removed by boot wash equipment).
- The boot wash equipment shall be suitably designed, well maintained and easily cleaned so that it does not present a source of microorganisms, which could be transferred to footwear.
- The minimum cleaning time and levels of detergent and sanitiser used shall be determined, documented and controlled to ensure effective cleaning of footwear.

All visitors and contractors entering the area will need to be provided with company issued footwear and follow the company rules; shoe covers are not satisfactory for high-risk areas (Anon., 2012). Captive boots should be cleaned in high-risk and manual cleaning and the use of an automatic washing machine have been found to give good results, achieving a 1–3 log reduction in viable microbiological counts (Taylor *et al.*, 2000).

The low-/high-risk barrier serves as the point at which work clothing needs to be changed. High-risk factory clothing does not necessarily vary from that used in low-risk in terms of style or quality, though it may have received higher standards of laundry (with completed microbiological validation and verification tests), especially related to a higher temperature

process (e.g. minimum of 71 °C for 3 minutes; Anon., 2012), sufficient to reduce microbiological levels significantly. Additional clothing may be worn in high-risk, however, to further protect the food being processed from contamination arising from the operative's body (gloves, sleeves, masks, whole-head coveralls, coats with hoods, boiler suits, etc.). All clothing and footwear used in the high-risk area is colour-coded to distinguish it from that worn in other parts of the factory and to reduce the chance that a breach in the system would escape early detection.

The use of antimicrobial textiles for factory uniforms has recently been developed. Once applied, antimicrobial materials offer a degree of protection against the growth of bacteria and odour control, especially if the clothing is occasionally damp or wet.

At the low-/high-risk barrier, a specific sequence of personnel entry is used. The following sequence has been suggested to maximize the control of pathogens on the hands, at the earliest opportunity, whilst reducing the need for frequent hand washing, which can lead to problems with dermatitis.

1. Remove low-risk/outside clothing and store in personal locker or designated storage area.
2. Remove low-risk/outside footwear and place in designated storage area.
3. Cross over low-risk/high-risk barrier.
4. Wash hands using antimicrobial soap.
5. Put on high-risk captive footwear.
6. Put on hair net, ensuring all hair is covered.
7. Put on outer clothing.
8. Pass through to high-risk area without touching door.
9. Apply alcohol to hands at entrance to high-risk work area.

To facilitate the required changing procedures at the low-/high-risk area barrier, the changing facilities have to be specifically designed. The high-risk changing room provides the only entry and exit point for personnel working in or visiting the high-risk area and a basic layout should accommodate the following requirements:

- An area at the entrance to store outside clothing or low-risk clothing. Lockers should have sloping tops to minimize dust collection.
- A barrier to divide the low- and high-risk floors. This is a physical barrier such as a small wall, which allows the floors to be cleaned on either side of the barrier without contamination by splashing between the two.
- Open lockers at the barrier to store low-risk footwear.
- A stand, on which high-risk footwear is stored, which also allows for the footwear to dry when it has been cleaned.
- An area with suitable drainage to carry out footwear cleaning operations.
- Hand wash basins, which have automatic or knee-operated taps, with water supplied at suitable temperature (comfortable to hands) and a waste extraction system piped directly to drain.

- Suitable hand drying facilities.
- Access for clean factory clothing and storage of soiled clothing. For larger operations this may be via an adjoining laundry room with interconnecting hatches.
- Alcohol rubs placed immediately inside the high-risk production area.

### 12.5.2 Assessment of hand hygiene compliance

Thorough hand washing is clearly essential to control transient microorganisms and should be assessed as a ‘critical’ process. In the majority of hazard analysis critical control point (HACCP) studies hand washing is seen as a prerequisite, though for some high-risk food manufacturing operations it may be seen as a critical control point (CCP). Assessment of hand hygiene could therefore be undertaken as part of routine hygiene testing or as CCP monitoring and verification.

The microbiological assessment of hand washing (total viable count), i.e. the concept that you can tell whether someone has washed their hands by swabbing their hands at random, is scientifically unfounded and is, therefore, wasteful of both time and money. This is because the levels of microorganisms on people’s hands (when clean) can vary from 100 to 10 million or more, though it is thought that the loading on people is relatively stable. This means that to take a single total viable count (TVC) of a person’s hands and get something meaningful from it, you must know the likely level that that person would normally have. To establish this would mean routinely swabbing all operatives and building up a picture of this ‘norm’, which in most food processing operations is impracticable. In addition to this, hand washing typically removes only 2–2.5 log orders of microorganisms. Therefore if one particular operative has a typical post-wash TVC count of 1000 microorganisms and on one day they had 100 000, whilst they clearly have more microorganisms than normal, it would not be possible to know whether they had not washed their hands. For example, before hand washing they could have touched some raw meat, contaminated their hands to a level of 10 million microorganisms and then washed their hands properly and reduced this to 100 000. Examining for the presence of Enterobacteriaceae or coliforms after hand washing may have a little more credibility, as coliforms are not part of the skin’s natural flora. However, again if somebody had touched raw materials (or routinely touches raw materials) and washed their hands, their coliform count could still be high after washing.

Microbiological methods for the assessment of hand hygiene that are acceptable, include looking specifically for a pathogen, e.g. *Staph. aureus*, with the purpose of excluding carriers from working in high-risk food processing areas if the HACCP study recognizes staphylococcal toxin as a risk. Such examination usually includes swabbing the hands after hand washing on three occasions and on different days. If the pathogen is routinely

present on the hands after washing, this person can be excluded from the high-risk area but is safe to work in low-risk activities. Alternatively, it is possible to assess the TVC level of the hands before hand washing and then afterwards to ensure that the operative has washed their hands sufficiently to ensure a suitable log reduction (e.g. 2 log orders) in microbiological count.

It has even been suggested that one technique would be to swab an operative's hands after they have washed them and, on leaving the processing area, to discard the swab immediately. The concept here is that whilst taking the swab may be technically pointless, the motion of going into production and 'swabbing' operatives to remind them of the necessity to wash hands is priceless!

The most common methods for microbiological assessment of hands include: swabbing using cotton tip swabs and sponges, imprinting the colonies of microorganisms present on the skin onto a solid medium such as an agar contact plate, and rinse methods which are capable of sampling the whole hand (glove juice) or the finger tips. Further details of all these methods can be found in Campden BRI Guideline No. 45 (Holah and Hall, 2003).

The measurement of ATP through bioluminescence on the hands is a useful marker of the overall cleanliness of the hands. Results are available in seconds, allowing immediate interpretation and corrective action if necessary. However, the use of ATP is not a direct replacement for microbiological testing and does not provide information on specific microorganisms. ATP swabs can be purchased ready to use from a number of different suppliers. Although each manufacturer of ATP swabs will have specific instructions for their use, the general principles are the same as those for microbiological swabbing. It must be noted that the relative light unit (RLU) value is specific to one manufacturer's test kit and luminometer. RLUs between different manufacturers' products cannot, therefore, be compared. To ensure the consistency of results, luminometers should be regularly serviced and controls should be undertaken.

Suitable non-microbial methods of assessing handwash compliance include visual monitoring by staff or the use of CCT cameras. It is also possible to install turnstiles and interlocked door arrangements such that the turnstile or door to the food processing area will only open when a recognized handwashing trigger has been activated, e.g. the water tap has run for 10 seconds. There are also more innovative methods to monitor personal hygiene compliance. A new patent assigned to the Procter & Gamble Company (Kennish *et al.*, 2011) describes its use of interactive packaging for development of personal hygiene habits. The interactive packaging system may include a plurality of usage monitoring devices, each configured to detect physical stimuli associated with the usage of the product, package or facility with which the usage monitoring device is associated. The system may be configured to determine whether individual

users are using product, packages or facilities appropriately. Another method invented by Melker *et al.* (2011) describes the use of a hand washing agent provided with a detectable, volatile compound, such as odours. After the hand washing event, the person's hands are exposed to a detector which is capable of detecting the volatile compound and indicating the use of the hand washing agent and thus hand hygiene compliance.

Hand hygiene compliance is still a very big issue in the food manufacturing environment. In studies of hand washing among food workers in food service facilities, compliance generally ranges from 5 to 60% (Todd *et al.*, 2010). Two main hygiene errors were identified: a failure to use soap (39% of attempts) and failure to dry hands adequately (42% of attempts). One compliance issue is the risk of skin damage from excessive washing or scrubbing, also unsupervised hand washing will never be completely compliant in any setting. The important issue is compliance by sanitation and maintenance employees, which very often is missed. The above methods can be used to increase hand washing compliance; however, it is important to remember about the basics: training, routine observation and feedback, making hand hygiene easy and convenient, reminders in the workplace, well-engineered facilities, avoiding overcrowding, understaffing and excessive workload, and rewarding, etc. Todd *et al.* (2010) also described a positive deviance approach which uses workers who want to change, improve or develop new ideas for enhancing hand washing compliance. Individual food handler behaviour is linked directly to the culture of the food business, and therefore an entrenched food safety culture is crucial for its compliance.

## 12.6 Conclusion

Personal hygiene policies and the facilities provided for personnel in food handling environments vary greatly. However, personal hygiene is one of the most important aspects of GMP and its implementation is required before completion of the HACCP plan. Personnel are both reservoirs and vectors of microorganisms and can act as a source of microbial contamination to food products. Therefore it is important to implement appropriate control mechanisms to reduce the risk of cross-contamination from personnel to the food products. A number of these mechanisms are listed in the chapter including: management responsibilities, training, factory clothing, hand hygiene, barriers between low- and high-risk areas, assessment of personnel hygiene, etc. Good hygiene practices and food safety culture should be maintained within personnel on all levels in food processing establishments. Whilst technically we have the knowledge, facilities and products to practice good personal hygiene, the challenge for the future remains in motivating food operatives to fully comply with established best hygiene practices and procedures.



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# 13

## Food hygiene and foreign bodies

M. Edwards, Campden BRI, UK

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**Abstract:** This chapter will consider the types of foreign bodies that are reported from food and how they get into the food. The control of foreign bodies will be considered in two main ways: firstly, methods for identifying foreign bodies in order to determine what they are and how they got into the food; and secondly, the various methods for preventing foreign bodies getting into food, and then detecting and removing foreign bodies from food products during food processing if they do get in. Finally, prospects for the future for each of these areas will be considered.

**Key words:** foreign bodies, metal detectors, X-ray detectors, optical systems, separation systems.

### 13.1 Introduction

Consumer complaints about foreign bodies are a continuing problem for the food industry. Recent years have seen an increasing emphasis on consumer rights, with frequent encouragement in the media for consumers to complain to food companies about incidents that would in the past have been viewed as trivial. There has also been greater support for complainants from government and enforcement authorities, including changes in consumer protection legislation. This has been combined with an increasing tendency towards litigation that appears to have spread to Europe from the USA, and the downturn in the economy in the last few years has led some to suggest that consumers see obtaining recompense for consumer complaints as a way of making money.

There is no doubt that over recent years consumer expectations with regard to food quality have risen dramatically, and this change in expectation has affected the view of foreign bodies as much as any other aspect of the quality of food products. Customers are therefore much less likely to accept foreign bodies than they were, say, 20 or 25 years ago. This can be attributed in part to a rise in 'consumer rights' over this period. However, the generally

increasing quality of food products over the same period has resulted in the occurrence of causes for complaint, such as foreign bodies, being much rarer than hitherto. The result of this is that these occurrences stand out much more clearly in the consumer's mind. Thus there is a certain irony in the food industry being to some extent the author of its own misfortune in the increasing numbers of complaints about foreign bodies.

This chapter will consider the types of foreign bodies that are reported from food and how they get into the food. The control of foreign bodies will be considered in two main ways: firstly, methods for identifying foreign bodies in order to determine what they are and how they got into the food; and secondly, the various methods for preventing foreign bodies getting into food, and then detecting and removing foreign bodies from food products during food processing if they do get in. Finally, prospects for the future for each of these areas will be considered.

## **13.2 The range of foreign bodies**

A foreign body may be defined as something that the consumer perceives as being alien to the food. The perception of the consumer is important, since not all foreign bodies are in fact alien to the food, though all have the potential to give rise to a consumer complaint. Hence foreign bodies can range from items that are demonstrably alien to the food, such as pieces of glass, metal or plastic; through items that are related to the food, such as fragments of bone in meat products; to part of the food itself, such as crystals of sugar or salt that are mistaken for glass.

### **13.2.1 Intrinsic and extrinsic foreign bodies**

It follows from the definition given above that the range of possible foreign bodies is virtually limitless. One commonly made distinction is between intrinsic and extrinsic foreign bodies. Intrinsic foreign bodies are those that are related either to the raw materials used in the food product itself or to the packaging materials. Extrinsic foreign bodies are those that are not so related, and become incorporated in the product flow from an external source.

Knowledge of the raw materials used in producing a food product and of the processing procedures used and packaging materials employed may give an indication of the most likely types of foreign body to get incorporated into the food as an intrinsic foreign body. For example, fragments of peach or apricot stone may occur in products made with these fruits. Similarly, an understanding of the processes involved in food production can also help in identifying likely origins of extrinsic foreign bodies. An example of this might be the fact that a liquid product is filled into a jar or bottle using a narrow nozzle, such that a fragment of plastic several centimetres across

could not have passed through the nozzle, but must have originated elsewhere. However, it should never be forgotten that in a modern food processing operation, the occurrence of a foreign body in the final product is the exception rather than the rule. It is therefore an indication that something unusual has occurred, and hence it is often necessary to stand back from the situation and suspend disbelief. Thus in the initial investigation all preconceptions as to what could or could not have happened need to be disregarded.

### **13.2.2 Sources of foreign bodies**

Foreign bodies may get into food at any stage from initial harvesting to final processing or even preparation and consumption by the consumer. Harvesting of field crops may result in pieces of soil, grit or stone being inadvertently collected with the crop. Weeds growing in the crop or at the edges of fields are important sources of foreign bodies, as are insects or other animals feeding on or amongst the crop plants. The crop itself may also be a source: for example, second year carrots that which get missed during harvesting can give rise to the occasional woody carrot amongst the following year's crop. Plant material may build up on harvesting machinery and then get incorporated into the harvested crop: this can be a particular problem with crops such as peas, where pea-shaped balls of pea leaf material may find their way into the product, and strongly resemble rabbit droppings.

Food processing should include procedures to remove foreign bodies incorporated during harvesting of the crop, but it can also give rise to foreign bodies itself. Many foreign bodies can be traced back to pieces of food processing machinery. Apart from the more readily recognisable items such as nuts and bolts, fragments of metal or other material from worn or misaligned machinery may become incorporated into the food. Plastic clips (Weasand clips), used to seal the contents of the animal's stomach during the slaughtering process at the abattoir, may occasionally find their way into meat products. Foreign material such as stones in the crop can lead to damage to processing machinery such as pumps, resulting in fragments of metal appearing in the product. Storage vessels such as tanks can lead to contamination if maintenance, modification or repair procedures are not carried out thoroughly: an example of this was fragments of weld slag found in wine after welding repairs to a storage tank had been carried out by an incompetent sub-contractor. Food factory operatives are a major source of foreign bodies, from stray hairs not contained by hairnets or beard snoods to studs or sleepers from earrings. Incorrect storage of raw materials and final products can result in infestation by food storage pests, resulting in the presence of foreign bodies such as insects or rodent droppings in the food.

Food packaging is a further potential source of foreign bodies. Offcuts of metal or plastic from packaging manufacture may sometimes get into

the empty food container before filling and become mixed with the food, and the breakage of glass jars or bottles on a filling line can lead to fragments of glass getting into adjacent jars or bottles.

The possibility that foreign bodies can get into food as it is being opened, prepared or even eaten by the consumer should not be overlooked. Fragments of torn or broken packaging material from the product may become accidentally incorporated in the food during opening, especially if the pack is difficult to open. Foreign bodies may be accidentally incorporated during heating of the product, such as chips of glass from previously damaged ovenproof glassware. A foreign body found on the plate amongst several different components of a meal may also be attributed by the consumer to the wrong food product. Sugar and salt added to the meal by the consumer have been mistaken for glass fragments. Lastly, consumers themselves may be the source of the foreign body, such as fragments of tooth or dental filling.

### **13.3 The role of good hygiene practice in managing these hazards**

#### **13.3.1 Quality management systems**

A good quality management system is vital to the effective prevention and control of foreign bodies in food manufacture. A structured preventive approach is likely to be the most reliable basis for such a system. The traditional approach of sole reliance on finished product analysis and factory inspection is nowadays unlikely to give acceptable assurance and customer confidence that the process is under control on a continuous basis.

#### **13.3.2 Hazard analysis**

Hazard analysis is the approach which all companies, whatever their size, should use to identify the points in their manufacturing operations which critically affect product safety. Foreign body hazard analysis of a food product process starts with the identification of the sequential stages in the process from raw materials and packaging materials through to the despatch, distribution and end use of the food product. These can then be summarised in a flow diagram. Each stage of the process is then considered separately and a number of questions are considered:

- Could any foreign matter be carried forward into this stage from the previous stage?
- Could any ingredient added at this stage include foreign matter?
- Could any packaging material applied at this stage introduce foreign matter?
- Could foreign matter gain access to the product at this stage from machinery, personnel or the environment?

The answers to these questions are then listed for each production stage and the options for preventive and/or detection and removal considered. Actions to be taken in the event of a problem should also be listed. Considerations such as the likelihood of a problem occurring, and the practicality, effectiveness and cost of the various solutions and the implications of a failure to remove the foreign material, both for the consumer and the company's commercial interest, all then need to be considered in deciding which, if any, of the options listed should be implemented.

Once the options have been decided, they should be installed, together with a means of monitoring to ensure that they are working effectively.

Smaller businesses may well be able to use the approach outlined above as part of a defence of 'Due Diligence' in UK law under the Food Safety Act 1990. The study should be carried out logically and thoroughly and carefully recorded, to provide written evidence of what has been decided and why. A commitment to review the options in the event of change or unforeseen incidents is also necessary. See also Section 13.4.

Larger businesses might reasonably be expected to use hazard analysis critical control points (HACCP), a more sophisticated version of hazard analysis. HACCP is dealt with in considerable detail elsewhere in this volume, and this section will only address its particular application to foreign bodies.

### 13.3.3 HACCP

HACCP is a more sophisticated version of the hazard analysis outlined above. In a similar manner to the more basic routine, a detailed flow chart of the various stages in the production process is drawn up and the various foreign body hazards associated with each stage are identified. Critical control points (CCPs) are then determined to focus resources at key points in the process. This does not remove the need for control at other points in the process, but highlights where the preventive or control measures *must* be effective. Three points are essential to any quality management system based on HACCP principles:

- Scheduled measurement or observation at a CCP that controls are working.
- Monitoring procedures to detect loss of control or trends.
- Detailed procedures to ensure effective implementation of controls and corrective action.

When the monitoring shows that conditions at a CCP have deviated from the specified critical limit, corrective action must be taken to dispose of the affected product (condemn, downgrade or rework, as appropriate) and avoid any recurrence.



A good quality management system should have built into it procedures for regular reviews of the way the system is operating and for consequent continual improvement.

Also associated with the quality management system should be procedures for staff training and education, both before and during employment. Training needs should be identified on a formal basis and collated into an overall training programme. This training should be recorded and noted in personnel records. Schedules should be prepared for the training of new employees as part of their induction, and the need for re-training of existing employees due to change in job, or move to another job, recognised as a management responsibility. It is important that employees have a clear understanding of the company's policy and works instructions, and have the right attitude to personal and operational hygiene.

However, none of this is of any use unless the company philosophy is correct and management is fully committed to quality at every level. This means instilling a quality attitude throughout the company, at all levels.

## **13.4 Methods of preventing foreign body contamination**

### **13.4.1 Design of factories and equipment and maintenance**

Good design and construction of food factories and good design and deployment of the machinery within are both essential for the elimination of foreign body contamination in the food product. Other chapters in this book deal more fully with this subject, but it is important that the influence of building and equipment design on foreign body contamination is taken into consideration. Good design can prevent the entry of 'active' sources of foreign bodies such as insect, rodent and bird pests, but can also prevent 'passive' foreign bodies such as bits of machinery from becoming incorporated with the product.

The building itself can sometimes be a source of foreign bodies. Flaking paint or damage to walls or ceiling should therefore be repaired immediately. Wooden parts such as doors or door frames need to be protected from impact damage to prevent wood splinters being produced and carried into the production area on trolley wheels or by personnel. Windows should be avoided in the production area if at all possible, but where they are unavoidable they should be protected from breakage or made from a non-glass material such as polycarbonate. Polycarbonate can also be used as a glass substitute for vision panels and instrument dial covers in food production areas, and for mirrors in changing rooms. Clear plastic covers should be used to protect all light fittings. Overhead services and fittings, beams and girders will accumulate dust and debris which may be dislodged, and may harbour pests, providing runways for rodents and perches for birds. The apparently obvious solution of boxing in such fittings can also give protection to pests: a false ceiling with no crevices and which is easier to

clean is often a better solution. Where overhead hazards are unavoidable, such as glass parts in fire sprinkler heads, the production line should be protected in some way, or moved to a position away from the hazard if at all possible.

The design of factory equipment is also vital. Surfaces of all materials and coatings should be durable and resistant to cracking, chipping, flaking and abrasion, and the use of wood within food processing areas should be discouraged because of the risk of splinters. Fasteners such as screws, rivets, bolts, etc., should be avoided as far as possible, especially over an open product line or vessel, in case they work loose. If they are unavoidable, they should be self-locking or locked using a thread locking compound. All equipment should be self-draining or have some means of removing residual liquid. Motors, bearings and shaft entry points should not be positioned over open product lines because of the risk of contamination, especially from lubricants or metal from failing bearings. Machinery should be designed such that material from the product does not build up in corners or crevices, only to break away later and become incorporated in the product stream. Conveyor belts need to be adjusted correctly and inspected regularly for wear to prevent contamination from the belt material, fraying webbing or fibres. Wherever possible, product lines should be covered to prevent foreign bodies falling onto the product. Precautions such as the inversion of containers and/or blowing out with an air blast immediately before filling can help to remove foreign bodies from containers.

#### **13.4.2 Prevention and control of insects, rodents and birds**

All food factories are potentially subject to periodic infestation by pests. Any type of foreign body is a cause for concern, but foreign bodies originating from insects, rodents and birds often cause particular upset and revulsion to the consumer finding them. With good pest prevention and control, the actual health risk presented by pest contamination is relatively low, but the perceived health risk is extremely high. Whilst the number of complaints of foreign bodies such as rodent droppings is low in relation to the number of products sold, the potential for adverse publicity and possibly prosecution is extremely high. Effective pest control requires:

- prevention, creating conditions in which pests find it difficult to enter buildings and/or breed within the premises;
- treatment, including regular inspection, rapid identification of the pest(s), and efficient application of appropriate control measures.

Pests enter buildings for the food, shelter, warmth and often water that they offer. Some control of pests can be achieved by preventing access to some or all of these, but they are often intrinsic to a food factory, and so pest control strategies must also include minimising the risk of entry and making conditions as inhospitable as possible for pests. The area surrounding the building should therefore be kept tidy and free from weeds,

stacked pallets and boxes or redundant equipment, all of which can provide cover for rodents. A path completely surrounding the building will often achieve all of these requirements. Similarly, the accumulation of waste (edible or otherwise) in the immediate vicinity of the building should be discouraged.

Birds can be discouraged from roosting on buildings by the use of bird deterrents. To prevent the entry of rodents, building foundations should be solid and taken down to at least 600mm below ground level to prevent rodents burrowing into the building. If it is possible for rodents to climb walls to get in, a band of 'non-friction' material may be applied one metre above the ground. Rough exterior finishes, and projecting quoins, buttresses and ledges can all help to give a foothold to a climbing rodent. Ventilator grilles and air bricks can provide points of entry to rodents, birds and insects and should be sealed with wire grids. Any cracks or crevices in the external walls should be repaired immediately.

Pests often enter buildings through doorways or window openings. To prevent rodents entering, all doorways should have a working clearance of no more than 3 mm, and flexible strip curtains can be used to prevent birds passing through doorways and other permanent openings. Spaces behind skirtings, architraves and mouldings, or loose wall or ceiling tiles can provide spaces for pest infestation. Rodents or insects can infest drains, and the use of 'back inlet gullies' will prevent rodents gaining access to buildings via the drains.

Whilst the design of the premises can do much to control pests, good housekeeping within the factory such as correct storage of incoming and outgoing stocks, stock rotation, general tidiness and removal of any food spillages are also very important. The arrangement of product flow through the building should be such as to avoid possible transfer of pests from incoming raw materials directly across to finished product.

Most food premises rely on the expertise of a pest control company or local authority to ensure that both premises and products are free from contamination. Whilst the introduction of an expert sub-contractor in this way will help to ensure that all the various aspects of pest control are covered, it does not absolve managers from the responsibility of keeping their premises free of pests. The contractor should therefore be chosen carefully and the basis of the work to be carried out should be fully understood between the parties. The contractor will be able to advise on the design of buildings and equipment, and should provide regular monitoring of pests together with immediate treatment when pests are discovered.

### **13.4.3 Incoming raw materials**

Incoming raw materials may be a major potential source of foreign bodies. Consideration therefore needs to be given as to the foreign bodies that may

be present in the raw material, and what measures may be needed to remove them. It may be worth specifying that the supplier is responsible for removing any foreign bodies before delivery. This is likely to cost more, and it needs to be considered whether the supplier is technically capable of removing the foreign bodies, and whether auditing of the supplier will be needed to ensure that the work is being done to a sufficiently high standard. The packaging of the raw materials may itself present a foreign body hazard. In the case of possible insect infestation, the question of quarantining incoming stock until it has been cleaned or can be shown to be free of contamination may have to be considered.

Packaging may also be a potential source of foreign bodies, from fragments of broken glass, through layer pads to pieces of string, staples, wire, plastic from thermoformed containers and offcuts of tinsplate from cans or caps. Again, the terms of the specification need to be agreed with the supplier, and consideration given to auditing of the supplier. Arrangements for appropriate storage of packaging materials to prevent deterioration or contamination during storage must be made, away from other materials that could contaminate or soil them. All packaging must obviously be clean at the point of use. All external wrapping materials such as layer pads should be removed carefully and disposed of properly. Packaging materials and containers should only be used for the purpose for which they were intended; a can 'borrowed' to contain a few screws by a repair technician may inadvertently be returned to the production line, together with some of the screws! Great care needs to be taken if packaging materials are recycled or reused that they are properly cleaned and free of foreign bodies before reuse.

#### **13.4.4 Personnel factors**

Personnel are a major potential source of foreign bodies in food premises of all kinds. Jewellery, hairs, pens and tools from personnel can all readily contaminate foodstuffs, but good recruitment, training, clothing and operating procedures can do much to mitigate the risk. It is important, therefore, that management understands this potential source and takes active measures to manage it. Recruitment of staff with appropriate attitudes and correct training at the start of employment and periodically thereafter are clearly essential. Provision of appropriate authorised clothing, including hairnets and beard snoods, for both staff and visitors, and rules regarding the wearing of jewellery can prevent many obvious foreign body problems. Standard operating procedures, such as pre-production hygiene checks and a ban on all loose items within the production area unless required for the work, will also reduce the risks. Provision needs to be given for designated eating, drinking and smoking areas, and changing, hand washing and toilet facilities. Clear rules are required to regulate who has access to production areas within the factory.

The success of any factory procedure depends upon the commitment of senior management to its application and use. The performance of all personnel in observing the factory hygiene regulations should be monitored so that appropriate action can be taken to ensure that the regulations are adhered to and foreign body contamination prevented.

#### **13.4.5 Distribution**

Foreign bodies may also enter food products during distribution to wholesalers and retailers. This can be controlled by ensuring that packs are properly sealed during production, that they are not mechanically damaged during distribution, and that pests cannot gain access to the product through the packaging. Food spillage on the packed product must be avoided to minimise pest activity. Storage areas and means of transport must be kept clean and free of pests. A tamper-evident pack design may be appropriate in some cases. Storage facilities must be appropriate to the product, and advice to wholesalers and retailers may be necessary, as well as storage guidelines on the pack for the eventual consumer.

#### **13.4.6 Catering**

There are particular foreign body hazards associated with catering establishments, combining as they do elements of the food production process with the hazards associated with the presence of consumers and with the serving and consuming of food. Where food is kept on open display, care needs to be taken to provide adequate protection of the food against foreign bodies being dropped on it, either by catering staff or, in the case of self-service establishments, by consumers. Whilst catering staff may be subject to operating procedures regarding the wearing of jewellery, protective clothing and blue plasters, ordinary consumers will not, and moreover will probably not have been trained in safe food handling techniques. Objects may also get into the food in the servery as a result of food preparation, e.g. from chopping, machine mixing, crockery or glass breakages or cross-contamination between separate dishes from lack of separate utensils. A common source of glass complaints in such establishments is chipping of shelves in glass display cabinets.

#### **13.4.7 Commercial factors relating to prevention of foreign body incidents**

The control of foreign bodies in food products has to be seen within the commercial environment in which it takes place. The criterion must therefore be to choose an approach to foreign body control in relation to the risks and costs involved. The choice of method will be influenced both by the size of the enterprise and the impact the cost will have on the

commercial viability of the enterprise. For example, a low-cost manual system may be the correct solution for a small operation, where a larger enterprise would perhaps install a machine. A low-cost manual system may be the appropriate solution when the problem is short term. The choice of equipment will depend on the technical problem to be solved, the cost of the equipment, the particular foreign body hazard and the risk involved. Assessment of the risk will involve not only the legal position but also the publicity risk to the business of a foreign body incident.

### **13.4.8 Investigation of foreign body incidents**

The investigation of a foreign body incident involves a number of clear stages. The first essential step is to determine all the known facts in the case. Unfortunately, when a foreign body complaint is made, the complainant is often in an emotional state, and this, coupled with often poor procedures for collecting information on complaints, results in a very incomplete set of information as to the circumstances of the incident. This is unfortunate for all concerned. The complainant may leave the store after making a complaint feeling dissatisfied, whilst the store has incomplete information and an unhappy consumer as well. It is therefore essential that stores and food manufacturers receiving consumer complaints do so in an organised and professional manner. Quite apart from the technical aspects, it is simply good customer relations, and may often defuse a situation which could rapidly get out of hand, whether the complaint is justified or not.

It is important that precise details of the circumstances under which the foreign body was discovered are recorded. In particular, it is essential to know whether the foreign body was found when the pack was opened, during food preparation or whilst eating the product, and whether or not the foreign body could have been heated during preparation or mixed with other food products. Any batch codes or dates on the food package should also be recorded, and if possible the packaging should be available for examination in case it shows evidence of how the foreign body got into the product. All data should be entered on a database of all consumer complaints. Such a database can be extremely helpful in identifying known patterns of complaints due to seasonal, raw material or other product factors, or in associating particular types of complaints with other variables such as the type of packaging used. It can also be helpful in identifying persistent complainants. When an individual consumer complaint is seen against the overall pattern of complaints, it is much easier to identify a new kind of problem or one that requires particularly prompt action.

The identity of the foreign body should be determined as precisely as possible by laboratory examination. It may be possible as a result of these tests to determine whether or not the foreign body has been subjected to food processing or whether it has been in contact with the food. It may also be possible to deduce whether it is likely to have originated with raw

materials, in the production, distribution or retail processes, or even from the consumer. The identity of the foreign body may give some indication as to whether this is an isolated incident, part of a pattern, or something that is likely to recur.

It may be important to determine the extent of possible contamination: this will depend on the type of foreign body involved and whether or not other, similar complaints have been received. If it is judged that there is a significant risk that other stock may be affected, decisions then need to be taken as to whether the situation can be controlled simply by isolating affected stock and preventing any more being sold, or whether a public recall will be necessary. Companies should have in place a recall procedure that can be immediately instituted if this is deemed necessary. Consultation with local enforcement authorities is recommended. In certain cases it may be worthwhile to check isolated or recalled stock using methods such as metal detection or X-ray scanning to identify the contaminated packs, after which it may be possible to re-distribute stock that is now known to be unaffected. Some manufacturers of suitable equipment are able to offer such a service. Finally, measures may be taken to prevent a recurrence of the incident, if appropriate.

#### **13.4.9 The law**

In the United Kingdom, the presence of a foreign body in a food product can constitute an offence under the Food Safety Act 1990 in that it renders the product to be 'not of the nature or substance or quality demanded' (Section 14). In addition, it may render the food 'unfit for human consumption, or be so contaminated (whether by extraneous matter or otherwise) that it would not be reasonable to expect it to be used for human consumption in that state' (Section 8). However, the same act also provides that it shall be a defence for a company to show that it 'took all reasonable precautions and exercised all due diligence to avoid the commission of the offence' (Section 21). What constitutes a due diligence defence is a matter for the Courts, and no absolute guidance can be given. However, larger companies may be expected to use more sophisticated and up-to-date systems than smaller ones, and may need to produce more detailed records. Nevertheless, a smaller company must still be able to demonstrate its diligence in taking measures to avoid the presence of foreign bodies in its products, even if the methods used are more basic and the checks more straightforward. As a minimum, it is likely that, for a due diligence defence to be successful, a company must be able to demonstrate that it has:

- considered what foreign body hazards might arise;
- judged the likelihood of the occurrence, the risk, the concern and the potential danger to the consumer;
- selected and installed controls which are demonstrably effective;



- integrated the controls into a whole plan;
- set up a review system for continuous improvement;
- maintained a full record of the above.

## 13.5 Detection and removal systems for foreign bodies

### 13.5.1 Approach: detection and removal versus separation

Approaches to the technical methods of combating foreign bodies on the food production line fall into two main categories:

- detection and removal systems;
- separation systems.

Separation systems are mechanical methods such as sieving and flotation that aim to separate foreign bodies from the food by exploiting basic physical differences. In many cases these methods are intrinsic to the production system itself. Possibly the most ancient is the process of winnowing to separate wheat from chaff, but more recent technologies have become much more complex.

Detection and removal systems, in contrast, are systems designed specifically to detect the presence of a foreign body in the food and remove it as a consequence of having discovered it. The oldest of these methods is manual sorting, whilst the newest such methods use extremely sophisticated electronic technology.

### 13.5.2 Equipment for detection and removal of foreign bodies

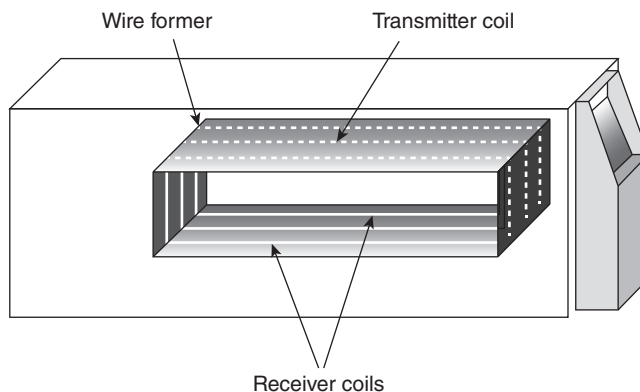
#### *Metal detection systems*

The first industrial metal detector was produced in the UK in 1948 by Bruce Kerr to salvage a large quantity of contaminated confectionery. Since then the demand for metal detectors has grown, particularly in the UK.

Metal detectors are of two main types. The most widely used is that based on the balanced coil system (Fig. 13.1), in which the food product being tested passes through an aperture surrounded by two receiver coils with a transmitter coil arranged between them. The transmitter coil is energised with a high-frequency electric current that generates a magnetic field. A metal particle travelling through the field disturbs it, and this change is detected by the two receiver coils.

The second type of metal detector is that based on the magnetic field system, otherwise known as the ferrous-in-foil system, in which the food product being tested passes through a tunnel or passage subjected to a strong magnetic field, which has the effect of magnetising any magnetic metal particle which passes through it. When the magnetised particle passes through the coils incorporated in the tunnel, a small current is generated in the coils, which is amplified by the electronics of the metal detector and





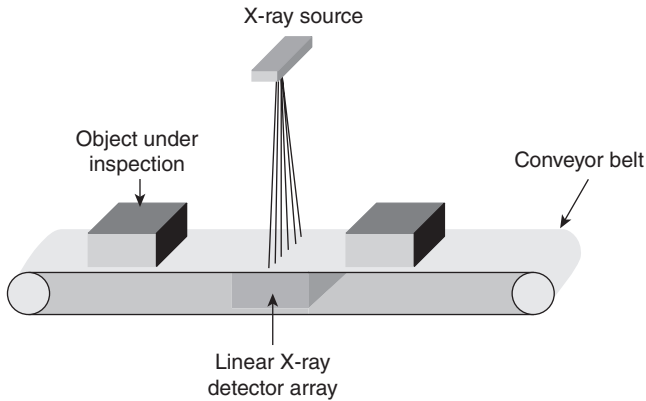
**Fig. 13.1** Schematic diagram of a balanced coil metal detector (from Campden BRI, 2004).

used to generate a detection signal output. Only magnetic metal materials (principally iron and steel) will be detected by this system, and so it will not detect non-ferrous metals and most (but not all) stainless steels. As a result of this, the application of this type of detector is mainly limited to food products packed in an aluminium foil pack or dish, where the presence of the aluminium does not interfere with the ability to detect iron or steel.

Metal detectors have a number of limitations. They will not detect metal particles below a certain size. Many food products, especially wet foods or those containing salt, are electrically conductive or have magnetic properties, reducing the sensitivity of the detector to metal fragments. Some metals are more readily detected than others, stainless steels and non-ferrous metals such as aluminium or brass being less readily detectable than iron or steel. The ease of detection of a metal fragment other than a perfect sphere will depend upon its orientation as it passes through the detector. Because of this, long, thin items such as needles or lengths of wire may be impossible to detect at some orientations. However, there is continuous research and development being undertaken to overcome some of these limitations, and metal detectors are becoming increasingly sophisticated and sensitive.

#### *X-ray detection systems*

All X-ray detection systems have the same basic components, illustrated in Fig. 13.2. All systems rely on the X-ray beam being either partially absorbed by the material through which it travels, in proportion to the density of the material, or on inducing fluorescence in the material through which it passes. In X-ray systems for food and pharmaceutical applications, the sample being examined passes through a fan-shaped flat X-ray beam about 2 mm wide on a conveyor belt. Beneath the conveyor belt is a linear array detector composed of a series of separate units. Each of the discrete units of the sensor array converts the energy of the X-ray beam falling on it to



**Fig. 13.2** Components of an X-ray detection system (from Campden BRI, 2004).

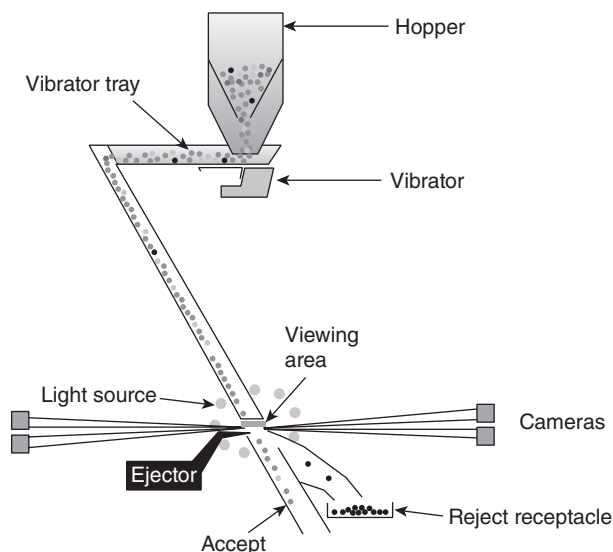
an electrical signal. The signal is passed through to a computer, which compiles a grey-scale image of the sample, line by line, as the sample passes through the X-ray beam. The image is then analysed by the computer and the sample accepted or rejected.

X-ray systems can be a relatively expensive option for foreign body detection, but can be tailored to detect a range of foreign body types that cannot be readily detected by any other method. They rely on there being a difference in X-ray absorption between the food and the foreign body. Many foods are water-based, and have a density similar to that of water. Thus dense items such as glass, metal, stone or bone are readily detectable, whilst most plastics, wood, insects, plant material and hair are not, because they have a density close to that of the food.

For many years the major barrier to development of this technology was the computer power needed to achieve the necessary speed of image analysis for realistic line speeds in a food industry environment. In recent years these problems have been solved, and the cost of this equipment has been reduced substantially. Further developments such as the development of twin-beam machines and the use of a combination of vertical and horizontal beams have improved the ability of the technology to detect foreign bodies hidden in corners or at the edge of packs, where the image of the foreign body tends to merge with the packaging.

### *Optical systems*

Optical inspection systems (Fig. 13.3) for food use take a number of forms, ranging from simple colour sorters to complex image recognition systems able to sort by shape. The product is fed towards the illuminator by a feed system in an appropriate fashion, for example aligning elongated products such as chips (French fries) so that they are orientated in a consistent manner. The illumination system will be tailored to the specific application,



**Fig. 13.3** Schematic diagram of an optical vegetable sorting machine (from Campden BRI, 2004).

and may include one, two or three different coloured light sources. Monochromatic units are only capable of sorting dark and light coloured objects, whilst the introduction of two or more colours allows more sophisticated functions. The product is detected by a detection system, which can vary from a simple diode to detect light or dark to an array of charge-coupled devices capable of creating an image. The signal from the detector is fed to the signal processing system, which again varies from a simple system able only to distinguish light and dark objects, to complex image-processing systems. Separation systems also vary widely, depending on the type of product being checked. Although no optical system is perfect, they can offer efficiencies from 85 to over 99% in some cases, and have a consistent level of effectiveness over a long period.

#### *Rejection systems*

All of the automatic systems outlined above require some form of rejection system to remove the product containing the contaminant from the production line. These have to be closely integrated with the detection system to ensure that the contaminated item is reliably removed from the product flow without taking large amounts of uncontaminated product with it. A range of methods are available, each of which has different applications and limitations. Some rely on some form of alarm, requiring an operator to respond to remove the offending package. Others use flaps, pushers or air blasts to remove the contaminated package from the line automatically:

these are usually integrated electronically with the detection system to ensure accurate timing. Having removed the package from the line, it is essential that it is held in a reject bin until it can be examined, investigated, recorded and disposed of by an authorised person.

### *Manual systems*

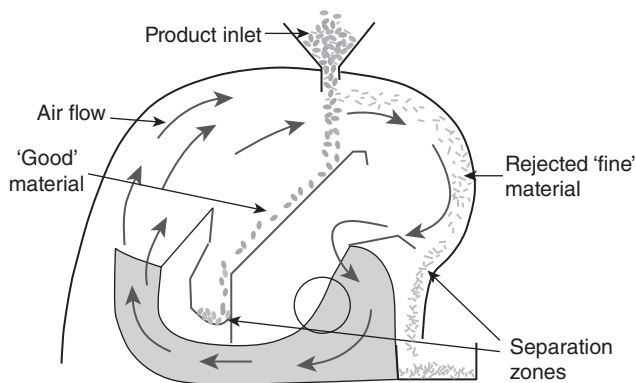
In general, humans are far more versatile and adaptable than machines, using up to five different senses and having the dexterity to manipulate the sample, coupled with the ability to make judgements. For short spells, therefore, humans can carry out inspection work to detect foreign bodies with great skill, care and sensitivity, and can readily adapt to new or previously unthought-of foreign body types. However, human inspectors cannot continue to work uninterrupted for long periods of time without a decrease in their efficiency. The efficiency of human inspection can be greatly increased by providing suitable working conditions, with factors such as good lighting, working height, belt width, colour and speed, and the density and depth of product that is presented for inspection. Inspectors should work for short periods of time, say 20–30 minutes maximum, to maintain inspection standards. Maximum efficiency levels between 80 and 90% can be expected.

### **13.5.3 Equipment for separation of foreign bodies**

#### *Air separation systems*

Air separation systems are dry cleaning methods that are rarely used in isolation, normally being combined with other removal systems. Air separation methods are relatively cheap and convenient, but care must be taken that they do not generate excessive levels of dust that might cause a fire or explosion. They are of two main types:

- Aspirators (Fig. 13.4) usually have specific applications for the separation of materials of different weights or densities such as the separation of chaff from wheat or shell fragments from nuts. A strong current of air passing through the product carries lighter material off, separating it from the heavier material. Specific gravity methods differentiate by density or weight when the impurities are of equal size and weight to the product. In contrast, air resistance used in selective aspiration draws a strong current of air through a thin stream of the material to be cleaned, carrying lighter particulates away.
- Abraders and graders are useful for removing surface contaminants of food material such as soil or husk. Dry scouring by friction or impaction using tumblers, vibrators, abrasive discs and rotating brushes are all variants of this general type. They are usually used in conjunction with aspirators to remove the loosened material.



**Fig. 13.4** Air separation by aspiration (from Campden BRI, 2004).

### *Liquid separation systems*

Liquid separation systems involve a wide range of wet cleaning methods, which are usually used in conjunction with other separation techniques. The washing of food is frequently one of the first stages of processing, particularly on agricultural crops. Common methods include the following:

- Washers and sprayers, in which the product is carried in or through clean water to remove light or surface contamination. Batch systems may involve tipping the product into a vessel and adding water before agitating and pouring off the dirty water, whilst continuous systems may involve spraying water onto the food as it passes along on a mesh, contaminants falling through the mesh with the water.
- Settlers and flumes are used to remove either light or heavy contamination. The density difference between food and water allows food to float off, whilst heavier contaminants sink to the bottom of the water. Foodstuffs may be carried along in a water flume, or may be left to soak in a settling tank. Settling tanks may be fitted with sparge pipes to produce air bubbles, which help to lift product to the top of the tank whilst soil drops to the bottom.
- Ultrasonic cleaning works by causing agitation of particles in a fluid, so loosening contaminants, which can then be removed by conventional separation techniques. However, this approach has limited use in the food industry.
- Centrifuges work by separating food material with different phases and different densities by centrifugal force. Perhaps the most well-known food application is not in foreign body removal, but the separation of cream from milk. The two principal systems used for foreign body removal are clarifiers, where the contents rotate in a rotating drum, and hydrocyclones, in which the rotation is achieved by a tangential supply to the stationary apparatus. In either case, the operating conditions have

to be chosen very carefully to optimise separation of the phases from each other.

All liquid separation systems are limited by the damage that immersion in water can do to many food products.

### *Sieves and filters*

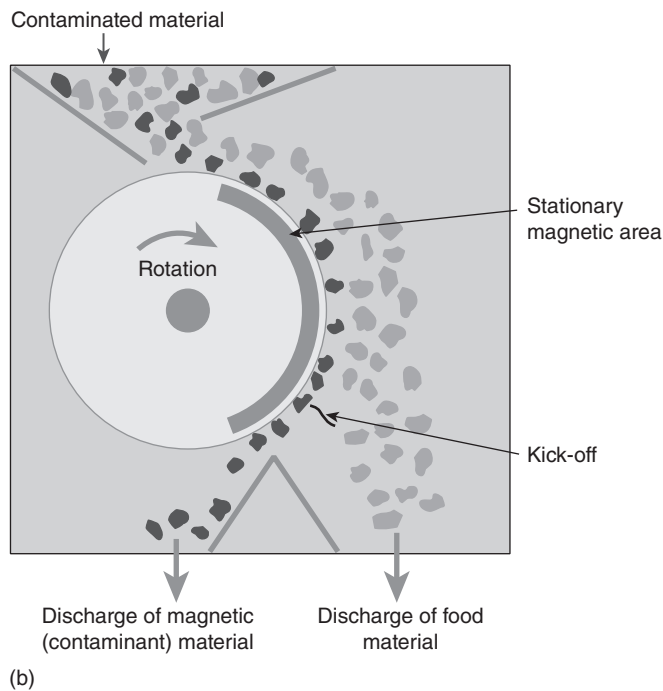
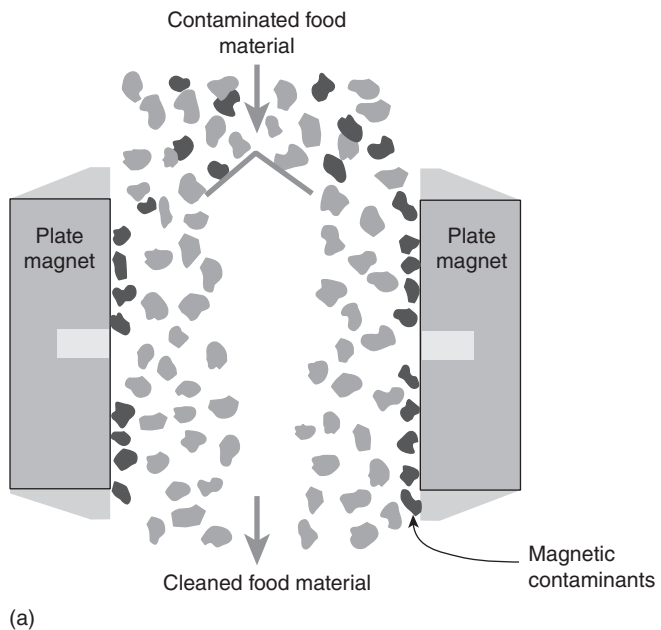
Sieves and filters remove foreign and extraneous matter on the basis of size, and are equally applicable to both wet and dry systems, to the full spectrum of food materials, and all levels of manufacturing output. They range from simple mobile hand-operated systems to integrated dedicated in-line installations. The simplest sieves are static grids, with meshes of any size, depending on the separation required. Other systems include perforated plates with square or round holes, which can be made from materials such as woven steel, copper or bronze wire. More complex systems can be built up, consisting of a series of meshes arranged vertically, horizontally or inclined. The sieving efficiency can be assisted by any combination of brushes, hammers, bouncing balls, aeration, or vibratory or rotary movement.

Sieves should normally be employed early in the process when used as a primary cleaner, because they are capable of removing a wide range of contaminants. However, they can be used at any stage throughout a process, depending on where foreign bodies are likely to occur. They cannot, of course, remove particles of similar size to the material being cleaned. Sieves are susceptible to mechanical damage, and also to blinding or blocking. Wet sieving can give rise to bacteriological and/or corrosion problems, whilst dry sieving can present a fire and explosion hazard.

### *Magnetic grids and permanent magnets*

Magnetic separators used in the food industry are normally powered by permanent magnets. Low-intensity magnetic fields from ceramic magnets (either barium or strontium ferrite) are used to attract larger ferrous particles such as nuts and bolts, whilst higher-intensity magnetic fields from rare earth magnets are required for attracting small or weakly magnetic particles, including rust scale and some stainless steels. There are four basic types of magnetic separator, some examples of which are shown in Fig. 13.5:

- Plate magnets are usually enclosed in a box, one surface of which acts as a magnetised plate. They are usually installed above conveyors or in the base of chutes, ducts, etc.
- Rod magnets are cylindrical permanent magnets placed in the product flow, either singly or in multiples, or built into grids through which the food material flows. The grids may be built into drawer-type assemblies for easy removal and cleaning. They are suitable for either dry or wet materials, but for powders with poor flow characteristics, the rods must be vibrated to prevent bridging.



**Fig. 13.5** Two different types of magnetic separator (from Campden BRI, 2004): (a) pass through separators with plate magnet separators; (b) magnetic drum separator.

- Pipeline traps are used for liquids transported in pipelines, and are arranged as groups of magnets through which the food must flow. Rod magnets may be used for liquids such as juices or soups, but plate magnets that do not impede the flow should be used for thicker liquids such as soups and stews.
- Magnetic drum separators consist of a non-magnetic rotating drum that contains a magnetic unit extending approximately 180° around the periphery. Typically this may form the end of a conveyor belt. Food material is fed to the top of the drum and non-magnetic material drops straight off whilst magnetic material is attracted to the magnet and held to it to the point where the magnetic field ends, at which point it is thrown off by centrifugal force. Separators of this type are used to extract contaminants from free-flowing materials such as grain, rice, tea and sugar.

Magnetic systems will not extract non-magnetic metals. The relative magnetic susceptibility of metallic materials in descending order is mild steel, magnetic stainless steel, rust scale, abraded non-magnetic stainless steel.

Unless the system is self-cleaning, the magnets in all systems will need to be removed from the line periodically and cleaned. Depending on the application, it may be desirable to keep records of the material removed from the magnet at each cleaning.

## **13.6 Conclusion**

While the available technology may not eliminate all foreign bodies from food, the correct application of technology will assist in removing many of them. The ability of the food manufacturer to prevent foreign body contamination once the product leaves the factory is limited, but even here, careful packaging design and attention to distribution conditions can do much to control the problem, as can careful wording of instructions to the consumer on the food pack. After removal and identification of the foreign body, the source can be traced more easily. Following identification of the source of the foreign body, control measures can be implemented, on the basis of a HACCP plan, which will assist in preventing a recurrence of the incident.

## **13.7 Future trends**

### **13.7.1 Future trends in foreign body types and complaints**

Great strides have already been made by the food industry in developed countries in reducing the numbers of foreign bodies occurring in food products. The types of foreign bodies that will be reported from food



products in the future will be governed by the materials with which the food comes into contact, and by developing technologies to prevent their introduction and aid their detection and removal. The materials with which the food comes into contact will be influenced by changes in the materials involved in everyday life, particularly those used in the construction of food harvesting and processing machinery, and in food packaging. An example of such a change in the past is the reduction in numbers of glass fragments occurring in food as a result of the breakage of jars and bottles on filling lines. This followed the introduction and enforcement of more stringent factory procedures after breakages to remove adjacent jars or bottles. Another example is the increasing numbers of complaints regarding plastic fragments as the use of plastics in food packaging and food machinery rises.

Since some consumer complaints undoubtedly arise from contamination in the consumer's home, whether accidental or deliberate, trends in the domestic use of various materials will also influence the level and type of complaints. This is almost certainly the cause of the continuing complaints of glass fragments in food, despite the precautions taken against glass contamination during food processing and packing.

### **13.7.2 Future trends in foreign body detection, removal and separation systems**

There are a number of possible techniques which may have application for foreign body detection and removal in the future. These include the following:

- Nuclear magnetic resonance imaging (NMRI). This system has been shown to be capable of imaging some foreign bodies within food. Any ferrous metals present in the product or packaging can distort the image, but aluminium foil can prevent images being obtained, particularly from within sealed containers. Plastics, paper and glass do not interfere with the image, but are difficult to detect. The images currently obtainable are not as clear as some other imaging techniques, but may offer potential for improvement.
- The application of ultrasound to foreign body detection is generally limited to situations where the detector can be placed in physical contact with a filled container, to produce an image which is then analysed to detect abnormalities such as foreign bodies. However, there has been research to investigate methods of long-range ultrasound where direct contact is not required.
- Microwave absorption, in which a thermal imaging camera measures the amount of energy absorbed by the product after microwave heating, may have applications in detecting foreign bodies within filled sealed containers.

- Differences between the dielectric constant of the food and the foreign body form the basis of a relatively new system in which the food passes through a pipe and is subjected to a microwave field. This method will detect a wide range of different foreign body types, including small pieces of plastic. This approach probably has more potential for development for the fast line speeds required by the food industry than most of the other possible methods, but is only applicable to liquid foods flowing in a pipe.

As indicated above, established methods such as metal detection and X-ray detection are still undergoing considerable development which will continue to enhance their capabilities, but they will always be limited by the laws of physics as to the general types of foreign body they are able to detect.

### **13.7.3 The future: foreign body identification**

The laboratory identification of foreign bodies reported from food will continue to be an essential part of the process of investigating foreign body incidents with a view to preventing recurrences. Increasing demands from consumers and enforcement authorities, together with the threat of adverse publicity and/or prosecution, are likely to increase the pressures for more detailed and accurate identification. This is likely to force food companies to make greater investments in the investigation of individual foreign body complaints, something that some companies have been reluctant to do in the past, believing that the costs of investigating individual complaints cannot be justified on commercial grounds. It will also lead to a greater emphasis on quality control procedures in foreign body identification, so that the results of such work can be relied upon, and will stand up in court. Initiatives such as the Campden BRI Foreign Body Identification Scheme (FOBS) will enable laboratories to demonstrate their competence in this work.

The methods used in foreign body identification have always come from a very wide variety of different academic disciplines, and therefore the methods used in the future will depend on developments in those disciplines. A particular area that has always provided methods for foreign body identification is forensic science, and forensic methods in the investigation of crime are becoming ever more sophisticated.

Those charged with the laboratory identification of foreign bodies will be aided by developments in microscopy techniques such as X-ray microscopy. However, probably the most important developments in the next few years are likely to be improvements in DNA analysis techniques, coupled with reductions in the present rather high costs of such work as more kits and reference material become available. This will enable much more precise identification of foreign bodies of biological origin, and it will

also become possible to obtain useful data from much smaller samples than hitherto, as DNA amplification methods become more widely available.

### 13.8 Sources of further information and advice

There are many sources of further information on hygienic design to control the presence of foreign bodies in foods. Some good general guidelines are given in Campden Guideline G5 (2004). The relationship between hygienic factory design and pest proofing measures is comprehensively detailed in Holah and Lelieveld (2011). Campden Guideline G5 (2004) gives much detail on the various methods of detection and removal of foreign bodies. Manufacturers of foreign body detection and removal equipment can also offer advice on the capabilities, advantages and drawbacks of the equipment they supply.

Advice on Quality Management Systems is also available from a wide range of sources, and many consultants operate in this subject area. Campden Guideline G42 gives a general introduction and guide to HACCP in the food industry. Campden Guideline G4 gives details of a wide range of methods for the laboratory identification of foreign bodies reported from foods. Advice on product recall is given in a report published by the BRC in 2007. This is a good practice guide, helping businesses to take corrective action to safeguard consumers from unsafe products.

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# 14

## Pest control in food businesses: an introduction

**L. Kloosterman, Optascan, The Netherlands and  
K. Mager, EHEDG, The Netherlands**

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**Abstract:** Integrated pest management (IPM) is a very effective method for controlling pests in food businesses with minimal use of harmful pesticides and other undesirable measures. This chapter explains how a pest control program based on this principle is designed and which materials can be used to detect and control pests before they become a nuisance. The chapter further discusses the registration and communication of pest sightings, pest detection and preventive measures.

**Key words:** integrated pest management (IPM), pest control program, vermin, pesticides, non-toxic pest detection.

### 14.1 Introduction

Consumers around the world assume that the food they buy and prepare every day is safely produced. Every day, many thousands of internal and external quality department employees work to monitor the safety of our food. Pest control is an extremely important aspect of this process because insects, as well as posing a microbiological hazard, are unpalatable to western consumers. Food businesses therefore do everything to exclude ‘unwanted visitors’ from their factories. There are three main points to consider for the control of pests in the food industry:

1. Pests should not be able to penetrate the building.
2. Pests should not be able to find food.
3. Pests should not be able to hide or nest in the building.

Ideally, pests should have no chance to penetrate the factory, but if this does happen the intruder should be forced to quickly leave due to a lack of hiding places and/or faulty machines leaking delicious snacks.

However, actual food storage facilities are rarely ideal and companies often have to work with old buildings and limited budgets. Sometimes the situation at the factory will be ideal but external factors will cause a problem (e.g. pests on surrounding land). Even new buildings are subject to continuous wear and occasional damage, which can lead to undesirable situations. Moreover, common pests are very opportunistic and know that where there are people there will always be something to eat.

Pest control therefore remains an important focus in a modern food plant, not least because governments and customers require very high standards from food production companies. A good pest control program is one of these requirements. This chapter describes what a good pest control program looks like and how it functions in a modern food business. It is based on integrated pest management (IPM) or the precept that 'prevention is better than cure'.

## **14.2 Integrated pest management (IPM)**

Pest control in food factories requires a variety of materials, all of which normally do not belong in a food business. Although it reduces the risk from live pests, pest control measures can give rise to issues such as dead rodents and insects, which are equally hazardous to consumers. Pest control is therefore a potentially hazardous process and must be carefully implemented and monitored.

### **14.2.1 Foreign materials**

In order to run a pest control program foreign resources and materials must be brought inside the factory; however, these resources and materials are sometimes harmful to humans and the environment and sometimes they are just clumsy; hindering the cleaning, as well as collecting dirt and dust. Toxic pesticides, mousetraps and electric fly catchers (EFCs) are examples of resources and materials used in controlling pests.

Materials that could be used to control pests:

- Should not end up in the product (food);
- Should not obstruct hygiene and housekeeping.

Although every pest control technician does his or her best to avoid (or at least reduce) these risks, they of course still exist. When more materials are used, the risk of the product being contaminated is increased, and hygiene and housekeeping are adversely affected.

### **14.2.2 Control results**

When a pest control program is effective, victims such as dead insects or killed or captured rodents inevitably accompany it, which also carries a risk.

Whilst unwanted living insects and mice must be excluded from food businesses, dead animals pose an equally damaging threat, particularly as we cannot always predict or determine where the carcasses end up. A consumer may not care whether the fly in his soup was already dead when it fell in, as he could become just as ill from the pathogens on a dead fly as those on a living one.

### **14.2.3 Conclusion: IPM**

IPM is a program that aims to prevent and control pests. It goes beyond closing windows and doors to keep insects out. The addition of 'integrated' to pest management indicates that the control, or more appropriately the prevention, of pests should be integrated into the overall business. In other words, it is essential that everything that happens in a food business is taken into account to ensure pest prevention. Hygienic design is very important here, but equally important is training and supervising staff and providing a sound and complete program for monitoring pest control.

IPM can be used to highlight and resolve errors and limitations of companies' buildings, logistics and production processes. It is designed to avoid having to employ a fire-fighting approach during a pest infestation so that harmful consequences can be avoided.

## **14.3 Pest control programs**

Modern pest control programs that operate on the IPM principle consist of a wide range of means by which pests are detected and controlled. A key characteristic of a good control program is that it does not look for just a control solution to vermin problems, but it also examines measures that could tackle the problem now and also prevent them in the future.

A good pest control program provides and communicates information so that preventive measures can be taken, resulting in pests staying out and meaning pesticide use is avoided.

### **14.3.1 Requirements for a pest control program**

Pest control programs in food businesses must meet two basic requirements:

- Problems with pests should be quickly detected and resolved.
- The program must meet internal and external legal requirements.

#### *Discovering and solving problems with pests*

How quickly pests are detected is dependent on many factors. Fruit flies and wasps are clearly visible, but cockroaches and many stored product insects can live in a hidden place and are only belatedly discovered.

Sometimes the pest control technician discovers the pest problems, but it is likely that staff, who are in the factory on a daily basis, will notice the first signs of pests. In the worst instances it is the customer or consumer who discovers the pest problem, which is a less than ideal situation but may also be a step in the process of discovering and solving vermin problems.

The process between discovering the pest and solving the problem consists of the following phases:

observation/detection → analysis/advise  
→ control/preventive measure → check

#### *An example*

During the weekly cleaning of an industrial bakery, bags of crushed oats were found to have gnawing damage and mice droppings were found in the raw materials warehouse (observation/detection). During a precise inspection by the pest control technician it came to light that, during the construction of a supply pipeline of flour, the crevice around the pipe had not been sealed properly. Signs like mice droppings and belly smears indicated that this was the entrance the mice had used to penetrate the building (analysis/inspection). The pest control technician recommended that the pipe should be sealed properly with a stainless steel plate (advice). The contractor in charge of the bakery then fixed the crevice (preventive measure).

Additionally, mousetraps were placed around the bakery to catch mice that might have already entered the warehouse (control). Extra inspections were also executed to ensure that mice no longer penetrated into the warehouse (check).

Obviously, pests that have penetrated a building must be detected as soon as possible, but it is also important that the time between the detection and the taking of any preventive measures is as short as possible. Good communication is therefore of great importance.

### **14.3.2 Legal frameworks and other rules**

The control of pests and the use of pesticides is usually strictly regulated, with the regulations varying between countries. However, it is likely that the use of toxic pesticides everywhere will be further reduced and that the focus on prevention will increase.

The involvement of governments in the control of pests is generally limited to the use of pesticides, and there is a legal use prescription by which everyone must abide. This is not so easy in practice, however, as some countries prohibit the preventive use of pesticides if no pest is present, even if pests such as mice are known to penetrate regularly. The preventive placement of toxic baits to control occasional mouse entry was commonplace for many years; however this is now a thing of the past in many countries.

Governments do not interfere with the content of pest control programs, but national inspection services will comment and impose sanctions if pests are found. How a problem with pests is resolved is of less importance, as long as it is done within legal frameworks. However, pest control must be part of any hazard analysis and critical control point (HACCP) program approved by the relevant government authorities and communicated to the workforce.

Of greater day-to-day influence is the role of food safety programs such as those from the British Retail Consortium (BRC), the International Food Standard (IFS), and the American Institute of Baking (AIB). These programs accurately describe how a pest control program must be implemented in order to be certified. Sometimes these food safety programs even recommend how to use detection means, such as EFCs and mousetraps, and where these devices are preferably placed. Supermarket chains and food producers themselves also provide very detailed specifications when it comes to pest control in the factories of their suppliers.

## **14.4 Contents of a pest control program**

In order to discover and resolve problems with pests while complying with all requirements, a sophisticated pest detection program, a comprehensive administrative program and good communication are needed. Pest control programs always consist of two parts:

- A practical part with monitoring devices and audits of pest control activities in the factory.
- An administrative section consisting of a (online) logbook containing all necessary forms, lists, procedures and maps, etc.

The administrative aspect is more or less standard for all food businesses, whereas the practice differs from company to company and must be tailored as such.

### **14.4.1 Inventory of the practical part: the risk assessment**

Standard pest control programs for food production companies do not exist. No one industrial building is the same as another, and different production processes and food products all bring their specific problems and risks. Furthermore, customer requirements and food safety programs must be taken into account and a thorough inventory must also be undertaken.

It is important to know which pest species may be a problem when a pest control program is developed. A pest control program should closely match the actual situation of the company and should quickly detect and identify penetrating pests, preventing the unnecessary and undesirable use of pesticides.



A risk assessment should be carried out by an expert in the field of pest control and an employee with expert knowledge of the company and its history. This is very important because some problems with pests are not always immediately visible or can be seasonal and so not appear on the inventory.

Every food company has a history when it comes to problems with vermin. The impact of major problems with pests can echo long after the problem has gone, and sometimes remnants of measures that have been taken are left long after a serious vermin incident.

During a risk assessment it is important to determine whether the current or historical risk image is still topical, together with the pest control program that goes with it. Sometimes excessive measures are taken or required to prevent a risk that, due to changed circumstances, is now less important or has even disappeared.

#### *An example*

A manufacturer of confectionery products produced nougat, some varieties of which were filled with nuts and dried fruit. A cargo of nuts contaminated with merchant grain beetles (*Oryzaephilus mercator*) was not discovered in time and was accidentally processed in the mixing department. The entire department, as well as the finished product, became contaminated, resulting in a costly cleaning of the entire factory. Even more serious was the recall of the product from stores to prevent any contaminated nougat bars reaching the public, which could damage the company's reputation.

Since this incident, and in response to these huge and costly problems, all raw materials entering the factory are double-checked. The pest control program was extended, with dozens of specially developed traps put in place to catch invading merchant grain beetles. In addition, the warehouse was sprayed with an insecticide every month to kill any beetle that had escaped the rigorous checks.

Today, however, nougat is no longer produced in the factory and nuts are no longer processed. In spite of this, the extra traps are still part of the pest control program and even the monthly spraying of the warehouse still takes place. There has been no realization that the use of the monitoring devices and insecticides is now no longer necessary.

In order to avoid these situations the inventory of risks must contain the following processes:

- desk research;
- analysis of products and processes;
- visual inspection;
- review current program/measures.

#### *Desk research*

In order to gain a good overview of a company, a thorough examination of all available data is very important. Often pest control logs are present,

along with important information about the activities of the current pest control company. Sometimes checklists or reports of inspections are still available, and it is important that there is open and free communication about these data. Sometimes looking into the reports of the current pest control company is prohibited, but, in reality, this is in no one's interest. An existing pest control program often offers a good basis to continue work, but not always.

Further to this, the experience of staff that are familiar with the company can be used to get a good impression of a company, and a conversation with an experienced worker often provides more information than an old log. Again, the employee must be free to speak openly and honestly about pest problems, both current and in the past.

### *Analysis of products and processes*

A good pest control technician can assess whether the products a food manufacturer processes brings additional risks of pests developing within or entering the factory. With each product comes its own specific risks, and readers are directed towards Chapter 15 for further information on stored product insects.

Sometimes it is not the processed products but instead the waste or by-products that pose additional risks. Potatoes alone, for example, are not particularly risky when it comes to problems with vermin. Potato waste (peel, purée), however, is particularly sensitive to fruit flies and owl midges.

Not only can products bring about additional risks, but some production processes are also more risky than others. Warm and humid production processes can cause problems with cockroaches, whilst dry and dusty areas often provide perfect circumstances for moths and other stored product insects.

In a thorough analysis of the products and processes in a food factory the relationship between the two should not be forgotten. For example, in a refrigerated section where flour is processed, the monitoring of tropical insects is not really useful as tropical insects stay dormant below 13 °C. In a warm warehouse, however, the monitoring of these kinds of insects is very useful.

It is very important that a pest control company knows and understands the circumstances, products and processes of a food company before they design a pest control program. Only then can they provide their customer with good advice about the use of monitoring devices.

### *Visual inspection*

In addition to the desk research and the analysis of products and processes, it is important that the pest control company carries out a visual inspection of the company in which the pest control program will be implemented. Armed with a torch and dressed in appropriate clothing (which may need to be provided by the company), a pest inspector should undertake a

thorough search for evidence of vermin, which may include looking within and underneath equipment, as well as the use of steps or ladders to examine surfaces above eye level.

The inspector must be free to speak with employees and it is preferable that they are accompanied by someone who has the knowledge and authority to access all parts of the building.

#### *Review existing programs/measures*

Once the risks of vermin are properly mapped, it can be judged whether the current pest control program meets the actual needs of the customer and whether some or all monitoring devices may be included in the new pest control program.

### **14.4.2 Program inventory**

During the inventory of risks it should become clear which pests are likely to become a problem. This information can then be used to determine which monitoring devices must be used and how often they should be inspected to minimize these risks, leading to the discovery and resolution of any pest problems as quickly as possible.

Potential problems with vermin determine what a pest control program will look like, but there are also other important factors to consider.

#### *Legal framework*

It is important to know what is and what is not allowed when it comes to pest control. Some pesticides are very effective; however, their use can be strictly regulated or sometimes even prohibited.

#### *An example*

For the detection and control of mice, toxic baits are often used. In essence, the presence of mice is detected and the detected mice are immediately eradicated. This is a particularly effective way of working. In many countries, however, the use of toxic pesticides is prohibited when there is no actual pest infestation, and the use of toxic bait to monitor and control mice without an actual infestation is therefore not permitted. In other countries, whilst not a legal requirement, this is often seen as a particularly green or sustainable practice.

Governments influence the form and appearance of pest control programs in different ways:

- Legal regulation of pesticide use.
- Legislation in the field of animal welfare.

In many countries the law provides strict rules on how pesticides should be used and how pests can be controlled. Pest control programs should take into account the fact that these requirements may vary from country to country.

*Requirements of quality management programs*

Many food companies are certified to quality programs such as the BRC, the IFS FSSC22000 or the comprehensive pest control requirements of the AIB. These standards define their own specific requirements when it comes to pest control programs in food businesses. In some cases these requirements dictate only a certain frequency of checks, but in other cases they provide a very precise determination of the methods and means that have to be used.

*Requirements of clients*

Increasingly, customers such as food retailers and food manufacturers implement their own requirements when it comes to pest control. These food retailers and manufacturers want to be absolutely sure that the products they have purchased are pest-free, but also that the pest control is carried out safely.

A good pest control program takes into account the specific requirements of internal and external quality programs and how they can be adapted when necessary.

**14.4.3 Pest control log**

A relatively standard part of pest control programs is the log containing all the relevant information about the program. Some information in the log is legally required, whilst other information is needed or required for the company's own purposes and to satisfy external quality assurance programs.

A pest control log may have the following contents:

- **General information**
  - Details of the pest control company
  - Diplomas or licenses of the pest control technician
  - Copy of the liability insurance of the pest control company
  - Name of the daily contact person
- **Materials and resources**
  - Overview of the applied pesticides
  - Statutory requirement of use of the applied pesticides
  - Material Safety Data Sheets (MSDS) of the applied pesticides
  - Labels of the applied pesticides
- **Activities**
  - Overview of the specifications of the pest control contract
  - Procedures
  - Annual evaluation
  - Planning
- **Monitoring devices**
  - Registration lists
  - Maps with location indicators
  - Statistics and trend analysis

- **Advice and corrective actions**
  - Notification of pest activity
  - Reports

Some pest control companies provide very extensive logs, whilst others record only the essentials. A good program, however, contains all the relevant information about the pest control program (not just the legally required information) and communicates this information quickly and clearly with all people involved.

## 14.5 Data collection

How well a company is informed about the pest activity on its premises depends on the collection and registration of data. Some data is spontaneously reported when an employee discovers vermin, whereas other data is deliberately collected during planned audits or the inspection of pest traps.

It is important that all gathered information is included in the pest control program. When there is a complete review of the pest control program, integral action can be undertaken to resolve pest problems or to prevent their emergence or escalation.

There are several ways in which information can be collected.

- visual inspection;
- notification of pest alerts;
- customer complaints;
- monitoring devices.

### 14.5.1 Visual inspections

Within most quality programs the periodic performance of good manufacturing practice (GMP) and good hygiene practice (GHP) should be audited. These inspections may be performed by the food company employees, but also by employees of a pest control company. The latest BRC guidelines (2012) are very specific about performing in-depth pest surveys by a pest control expert, and the purpose of these inspections is to provide an overview of the company in terms of all aspects of the pest control program, including cleaning, good housekeeping, the layout of the building.

Inspectors often attempt to allocate a score to these inspections so an upward or downward trend can be observed, but, in practice, this proves to be very difficult. Visual inspections are inherently subjective because each inspector has his or her own focus, and factors such as the background and experience of the inspectors play a very important role.

Additionally, each inspection has to be placed in its own context. For example, if an inspection is undertaken in autumn or winter many kinds of

pests, such as insects, are relatively dormant, whereas if an inspection takes place in the summer many species of insects are evolving.

Sometimes visual inspections are performed using a checklist, but usually they involve a 'free' visual inspection, which includes all matters to do with overall hygiene and good housekeeping.

#### *An example*

A food business uses a pest control company to perform a quality inspection every 6 months, and the inspection examines various issues that can attract vermin. The company produces confectionery food products that also end up on the floor and are washed away, resulting in the presence of confectionery residues in the drain wells.

During the inspection in the spring dirty drain wells were detected, but the report only commented that the drains had to be flushed more often. During the inspection in late summer wasps and ants were discovered in the drain wells, and in some drain wells fruit flies had laid eggs. The food company scored sufficiently high in the spring and less sufficiently in the late summer, even though the circumstances (dirty drain wells) do not differ substantially.

Visual inspections are a valuable addition to pest control programs because it requires more than just looking for traces of vermin. However it is difficult to provide an objective value on which you can judge the results of such inspections.

### **14.5.2 Notification of pest alerts**

Pest control technicians are regularly present in food businesses, depending on the frequency of visits that has been agreed upon (6-weekly, monthly and sometimes weekly); however, these visits are only periodic. The employees of food businesses, in contrast, are present every day, including the times when it is quieter and pests (such as mice) find it safer to emerge. Hygiene staff clean and maintain machinery and open equipment such as empty silos to inspect and clean them, and they often spot vermin in places that are usually inaccessible for external pest technicians. As a result, the food manufacturer's staff are an invaluable source of information on the pests.

In addition to this, house staff often know more about the larger and recurring problem areas, such as mice using the same hole to gain entrance. This information must be captured and used to improve the identification of pest problems and to suggest structural solutions.

Good pest control programs offer staff the opportunity to report and register the pests they have seen, so the pest control technician knows what pests are present and where they are most frequently spotted. Often the registration of notifications of pest alerts appears in the front of the log in a form (list), which the pest control technician reads and signs to acknowledge

it. There are also pest control programs that offer online registrations for pest sightings, and these programs do not only notify the pest control company, but also all personnel involved.

### 14.5.3 Complaints

Unfortunately, traces of pests such as mouse droppings and dead insects are sometimes found in food products. The producer of the food is not always responsible for these problems (pests may have entered the food packaging after they have been opened), but in most cases they are blamed first.

Complaints about pests in or on products should therefore always be treated very seriously and must be carefully recorded. An accurate registration of the complaint is essential in discovering the potential source of the complaint.

The following information is important in handling a complaint regarding (traces of) pests in food products:

- The date on which the product was manufactured and packaged.
- The kind of vermin present.
- When the complaint concerns insects, it is important to determine in what stage of development the insect was found.
- Under what conditions (temperature) the product was transported and stored.
- When and where the product was opened.

Most food producing companies have a traceability program, and these programs can help a lot when trying to locate the source of a pest problem.

If it is plausible that the cause of the complaint actually lies with the producer of the infested product, preventive measures can be taken to prevent such complaints in the future. Complaints about vermin in food products should always be included in the pest control program, and the reports of these complaints must always be traceable so that in any subsequent complaint they may be consulted again.

### 14.5.4 Monitoring devices

To detect and control pests in food businesses many monitoring devices are available. These range from the traditional mousetrap to all kinds of insect traps with chemical attractants (pheromones), in which very specific types of insects can be caught.

As part of the IPM philosophy, pest control and detection also bring associated risks, which must be properly weighed if the applied monitoring devices do not add more risks than they can possibly solve.

#### *An example*

A company that processed flour products was concerned about contamination by confused rice beetles (*Tribolium confusum*). In order to detect these

small beetles, dozens of small glue traps with an attractant pheromone were placed throughout the company. The glue traps were placed in the most critical (and dusty) spots and were monitored monthly.

Audits repeatedly showed that the glue traps were often completely filled with flour dust. A small test showed that the glue in most of the traps lost its stickiness after only one day. In practice, the glue traps hindered the cleaning and even caused additional pollution. The glue traps were removed and replaced by visual inspections of the most critical places.

If monitoring devices are used to detect pests in food companies, a few conditions must be met:

- The hazard that is to be detected must be real.
- The monitoring devices must not form a hazard.
- More monitoring devices than necessary should not be used.
- The monitoring devices must be placed and checked within the legal framework of the country concerned.

Monitoring devices must be placed at a fixed location, equipped with a location indicator (usually an arrow sticker) and fixed to the wall or floor. Monitoring devices are explained below.

### **14.5.5 Rodents**

#### *Baits for rats and mice*

In many food companies, the presence of rodents is detected by the placement of toxic or non-poisonous baits at different locations in and around the buildings. If mice or rats gnaw on the bait, this can be detected and registered and action can then be taken to control or prevent rodents entering or nesting.

Rat and mice baits are usually only put in place for the detection of mice and rats that tend to penetrate buildings, such as house mice (*Mus musculus*), black rats (*Rattus rattus*) and brown rats (*Rattus norvegicus*).

Bait, usually in the form of pressed grains and cereals, is placed in tamper-proof closed boxes inside and around buildings, although so-called 'block' baits are increasingly used since it is clearly visible when rodents gnaw on these blocks, and they tend to spread less easily when the bait box is tampered or damaged. Rodent baits are usually checked 8 or 12 times every year. In cases where the presence of rodents is known, these baits should be checked more frequently. The legal prescriptive use of the bait must be followed, which may require multiple checks per week.

#### *Traps for rats and mice*

In places where the use of bait is not permitted or possible, mechanical rodent traps can be used. Mechanical traps for mice and rats are more frequently used inside buildings, as the use of toxic baits is less controversial outside buildings.





**Fig. 14.1** Single catch mousetrap.

There are three different types of rodent traps in various versions:

- single catch rodent traps;
- multiple catch mouse traps;
- glue traps.

#### *Single catch rodent traps*

This kind of trap can, as the name suggests, catch only one rodent at a time. Everyone is familiar with the old trigger trap to which a block of cheese can be attached. Modern single catch rodent traps work in the same way and rat traps are bigger than mouse traps (Fig. 14.1).

Rodent traps used in pest control programs are usually placed in a sealed box. Rodents are more likely to crawl into a closed box and trapped rodents remain out of sight. Single catch rodent traps are checked at least weekly. When mice or rats are caught, this must be recorded in the pest control program.

#### *Multiple catch mouse trap*

Multiple catch mouse traps can catch multiple mice simultaneously (Fig. 14.2). In such events, it is intended that the captured mice (multiple traps to catch rats in pest control programs are virtually never used) stay alive for release or humane disposal.

In practice, however, caught mice are often found dead due to stress or injuries. Multiple catch traps are available in various forms; some have



**Fig. 14.2** Multiple catch mousetrap.

a simple seesaw mechanism, but other types have more complex trigger mechanisms. Multiple catch rodent traps are also monitored weekly. When mice are caught this must be recorded in the pest control program.

There are many types of mousetrap, both single and multiple catch. There are traps in which mice and rats drown in alcohol or water and traps with a range of choking mechanisms. However, these types of traps are not often used in the food industry.

#### *Glue boards*

A common and effective mousetrap is the glue board. Glue boards are plastic or cardboard plates or bowls covered with glue, on which mice and rats walk and then stick to. Glue boards should only be used when there is a serious mice or rat infestation. Preventive placing of glue boards is not in common use and glue boards must be placed on the floor to be effective. On the floor glue boards get dirty and dusty and therefore quickly become less effective.

Glue boards are checked at least daily, but preferably more often, and are removed when mice are no longer being caught. When mice or rats are caught this must be recorded in the pest control program. In some countries the use of glue boards is restricted by law as this trapping method can be considered to be inhumane.

#### 14.5.6 Insect traps

To detect insects in food factories a variety of traps are available; however, not all traps are equally suitable for food use. Insects are not only caught to prevent them from causing damage, they are also caught to spot trends and track specific insects such as stored product insects.

##### *An example*

In a snack food company EFCs with a sticky roll were used. The sticky roll revolves slowly so there is always a fresh piece of adhesive available, and the rolls last for approximately 6 months. To meet the requirements of the quality program, the EFCs were checked four times every year. The visible insects were then counted and determined.

In a warehouse a stock of salty biscuits was stored too long and became infested with drugstore beetles (*Stegobium paniceum*). These beetles can fly and some were caught in the EFCs in the warehouse.

Before one of the checks of the EFCs, the weather was bad and the beetles remained inactive because of the low temperatures. No new beetles were captured by the EFCs and the previously captured beetles were covered with fresh sticky roll, and as a result the beetles were not noticed during the check of the EFC. Essentially, therefore, the EFCs caught the beetles, but no one detected them.

It is important to remember which monitoring devices are suitable in the specific situation of different companies. For example, it is of little use to place insect traps in cold (below 10°C) storage rooms, as the above example shows that these insects are not active at low temperatures and are therefore not captured.

Note that common flying insects such as house flies and mosquitos fly when it is colder, so it is advisable to place EFCs in cold rooms, where these kinds of insect can cause the majority of problems. A list of the most common insect traps is now given.

##### *EFCs*

EFCs have always been used to catch flying insects. Increasingly, they are also used to discover trends and identify problems with flying insects. Not only insects that usually live outdoors are caught, but also insects that tend to stay inside and develop in waste or food storage areas, such as stored product moths and fruit flies. EFCs use UVA light to attract insects and then various methods to capture or kill them.

It is possible to equip EFCs with extra lures to attract insects. Certain types of EFCs use CO<sub>2</sub> to lure mosquitos, and others use pheromones (sex attractants) to attract specific insects such as moths.

EFCs need to be inspected at least four times a year. The trapped insects are then counted and the species determined. Increasingly, however, EFCs are inspected 8, 12 or even 52 times every year and the results are recorded in the pest control program.

*Correct location of EFCs*

There are many opinions about where electric flycatchers should be placed, but the following rules are generally universal:

- EFC lamps should not be placed over or close to open products. This is because they can bounce back from the electric grid and contaminate the product.
- EFCs should be placed near entrances and passageways. However, the lights of EFCs should not shine outwards to prevent unnecessary luring of insects.
- EFCs must be placed in a way so that maintenance and cleaning is easy and safe.
- EFCs should not be placed in or near a strong draught.

Several different types of electric flycatchers are available depending on their trapping mechanism.

*EFC with electrocution grid*

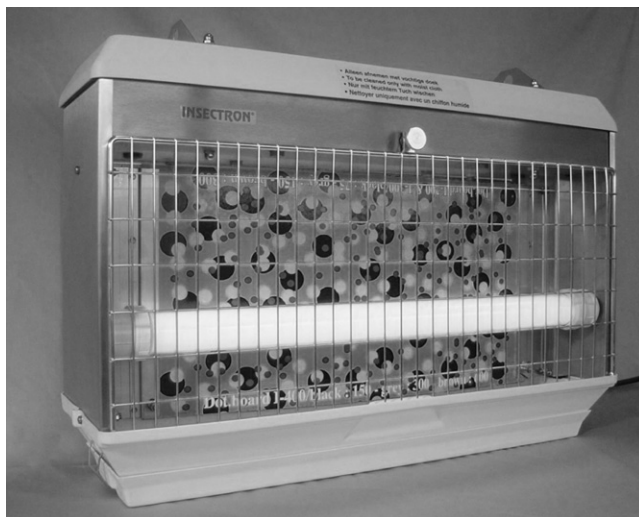
Many of the EFCs in use today are fitted with an 'electrocution grid'. These grids use a high voltage to electrocute flying insects when they touch it.

- Benefits:
  - Large capacity.
- Disadvantages:
  - Small insects are not always killed.
  - During the electrocution, parts of the insects can become aerosolized and can contaminate the surrounding area.
  - Killed insects in the collection tray and on the grid can contaminate the surrounding area.
  - Killed insects can ignite and cause fires.
  - Killed insects are difficult to count and identify for analysis and trends.
  - The spark from the electrical grid can ignite dust or gas, leading to explosion.

*EFC with glue board*

Food companies increasingly employ EFCs that use an adhesive sheet to catch flying insects (Fig. 14.3). These types of EFCs also use a UVA light to attract insects, which are then caught on a sticky sheet and cannot escape.

- Benefits:
  - Small insects are also caught.
  - The trapped insects cannot contaminate the surrounding area.
  - Captured insects can easily be counted and identified for analysis and trends.
  - Electric flycatchers with glue boards are fireproof, and some types may even be used in hazardous areas.



**Fig. 14.3** Electric flycatcher with dotted glue board to attract more insects.

- Disadvantages:
  - Small capacity (depending on the type).

#### *EFC with glue roll*

Some types of EFCs use a glue roll to catch insects. The glue roll rolls off slowly and renews itself constantly. Captured insects are neatly packed into the roll.

- Benefits:
  - Large capacity.
  - Small insects are also caught.
  - The trapped insects cannot contaminate the surrounding area.
  - Electric flycatchers with glue boards are fireproof.
- Disadvantages:
  - Captured insects are difficult to count and identify for analysis and trends.

#### *EFC with fan*

Some EFCs use a UVA light to attract insects and an integrated fan to blow the insects into a tray or basket, where they desiccate.

- Benefits:
  - Large capacity.
  - Small insects are also caught.
  - The trapped insects cannot contaminate the environment.
  - Electric flycatchers with a fan are fireproof.

- Disadvantages:
  - Captured insects are difficult to count and identify for analysis and trends.

#### *Insect pheromone traps*

Pheromone traps are often used to catch certain species of insects (mostly stored product insects), and in these traps a pheromone attractant is used to lure insects. Once attracted, a sticky board or catching bucket captures the insect.

Pheromones are sex attractants which attract only males of various species of insects. These types of trap are not used to control insects (females remain alive), but instead are used to demonstrate the presence of insects. Many different types of insect pheromone attractants are available, including:

- the clothing moth (*Tineola bisselliella*);
- the Mediterranean flour moth (*Ephestia kuehniella*);
- the cacao moth (*Ephestia elutella*);
- the Indian meal moth (*Plodia interpunctella*);
- the tobacco beetle (*Lasioderma serricorne*);
- the carpet beetle (*Anthrenus verbasci*);
- the confused flour beetle (*Tribolium confusum*).

Since many of the insects that are attracted by pheromones live in a dusty environment, the use of glue boards to capture these insects is less suitable as the glue often dries rapidly under dusty conditions. Glue boards can therefore only be used when they are checked and replaced very frequently.

Insect pheromone traps are inspected at least 8 times a year, and the trapped insects are then counted and the species determined. The results are recorded in the pest control program.

#### *Insect traps with non-toxic attractants*

To catch and detect insects food attractants are also used. The use of lemonade traps in the late summer to keep the patio free of wasps is common in domestic environments. The insect traps that use food attractants can be fitted with a glue board or bucket to trap insects. In places where many insects have to be caught (such as barns), glued ropes and ribbons are sometimes used.

Insects that are usually caught using food attractants include:

- cockroaches;
- wasps;
- fruit flies;
- common house flies.

Insect traps with non-toxic attractants are inspected at least eight times a year. The trapped insects are then counted and the species determined. The results are recorded in the pest control program.

*Fixed inspection points*

Critical places where it may not be possible to use insect traps (for example a collection bin of an exhaust installation or inaccessible places where dust can collect) must be checked regularly as contamination by pests can easily occur. These sites can be monitored periodically, according to a fixed schedule, usually at least eight times a year. Detected insects are then counted and the species determined. The results are recorded in the pest control program.

**14.5.7 Recording of collected data**

During the inspection of a food factory and its associated monitoring devices much information is collected. This information should be clearly recorded and made available for analysis. It is important that all insect traps, EFCs, rodent traps, etc., are individually mentioned on registration forms, in order to allow for a thorough analysis of the collected data.

The use of a checklist (Fig. 14.4) is only the beginning, however. The collected data should be analyzed, and thanks to the increasing digitization of collected data, statistics analysis is now easier.

**14.5.8 Building plans**

In the pest control program building plans must be readily available, as all monitoring devices must be marked on them. Pest control programs may also have interactive building plans that show not only the location of the monitoring devices but also immediate statistics and pesticide use.

The following should at least be present in a building plan:

- The date the drawing was made.
- The date of the last modification.
- A key to the symbols of the monitoring devices.

**14.5.9 Statistics**

Good pest control programs generate three different statistics:

- Statistics for each monitoring device (electric flycatcher, mouse trap, insect trap, etc.).
- Annual statistics.
- Long-term annual statistics.

A simple and effective way to express these results is graphically, as shown in Fig. 14.5.

*An example*

The above statistics show that rodents visit rodent bait stations around the building throughout the year, and the written reports states that

CHECKLIST INTERNAL BAIT STATIONS  
MICE

Name: Food Factory  
Location: London

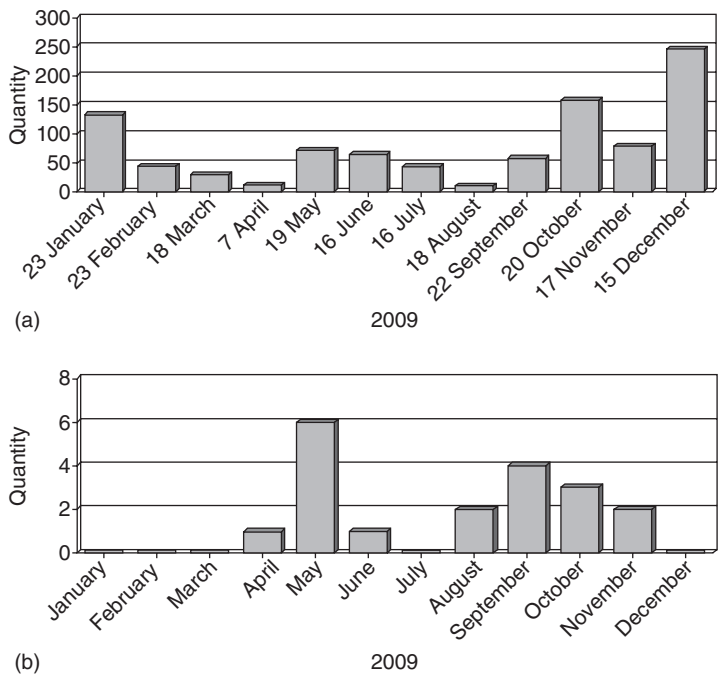
List number. 1/2010

Department		Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
Warehouse	1														
	2														
	3														
	4														
	5														
	6														
	7														
Warehouse second floor	8														
	9														
	10														
Loading	11														
	12														
	13														
	14														
Transfer Area	15														
	16														
	17														
	18														
	19														
Restaurant	20														
Workshop	21														
	22														
Boiler Room	23														
	24														
Cellar	25														
	26														
	27														
	28														
	29														
	30														
Signature															
Client															

**Fig. 14.4** Example of a simple check list on which each bait station for mice is individually listed and every single check can be recorded. Such a list can also be made for insect traps, electric flycatchers and, for example, fixed inspection points.

predominantly mice feed on the presented bait. Inside the building mice are caught by mechanical mousetraps. There is a peak in May, which is surprising because rodents usually invade in autumn and winter. This can also be concluded from the feeding at the bait stations outside, and from





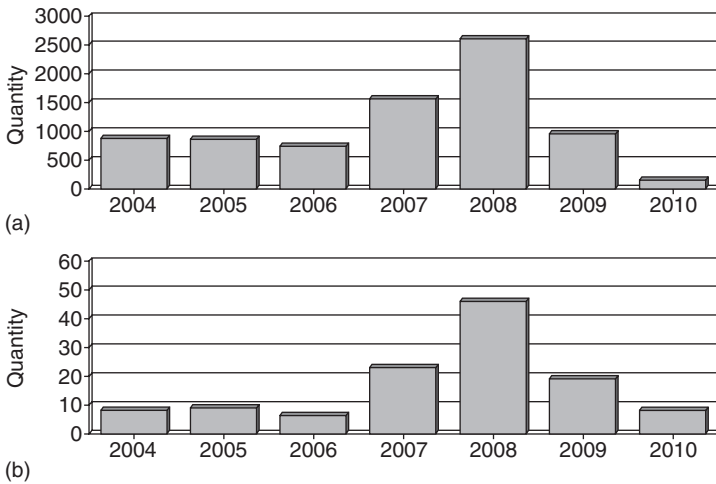
**Fig. 14.5** (a) Feeding by rodents from bait stations outside the building and (b) mice caught in mechanical mousetraps inside the building.

January to April the feeding decreases while from August a rise can be seen again.

Is the capture of mice in April, May and June an incident, or could this indicate that there was a problem with the structure of the building in the spring months? In order to address this it is important to look at long-term annual statistics (Fig. 14.6).

The long-term annual statistics show that the feeding at the bait stations outside the buildings in the last 6 years runs more or less parallel with the catching of mice inside. In other words, if more mice live outside, more penetrate the building. In 2009 there was an exceptional situation in the spring, but throughout the rest of year fewer mice were caught. More research into this is needed.

Research into the above situation pointed out that in April 2009 a load of raw materials with some mouse nests between the packaging was supplied to the premises. This was fortunately discovered, but some mice had invaded the building, although the rest of the mice stayed outside and fed on the bait in the bait stations. This explained the slightly increased feeding from the bait stations outside.



**Fig. 14.6** (a) Feeding by rodents from bait stations from outside the building (2004–10) and (b) mice caught in mechanical mousetraps inside the building (2004–10).

#### 14.5.10 Analysis and interpretation of data

The above example shows that data collected by the pest control company and additional research can detect and resolve the structural causes of problems with pests. In the introduction we stated that problems with pests in general are caused by the following:

- pests can enter;
- pests can find food;
- pests can hide.

The data on pests collected by the pest control technician must always relate to these three factors. Therefore, it is important to accurately register the species of pests that have been detected and where they occurred.

All results must be discussed and analyzed periodically. It is important that the food company's staff, who know the business well and are able to establish a connection between the presence of the pests found and the situation in the company (now and in the past), are involved.

#### 14.5.11 Types of pest

After vermin is detected it must be identified. Is it an indigenous species or is it an exotic species that usually lives in other parts of the world? It is also important to know whether the detected pest usually lives inside or outside buildings. It should be noted that many insects from (sub)tropical regions appear so frequently that they can almost be called indigenous.

One example of this is the German cockroach (*Blatella germanica*), which lives permanently in many homes and bakeries in western Europe, but originates from warmer areas.

Captured pests can be divided into three groups:

- pests that live and develop outside (indigenous);
- pests that live and develop inside buildings (indigenous or exotic);
- pests that live and develop in products (often exotic).

If the presence of pests is confirmed, a solution must be found immediately.

The solution always consists of two parts:

- Addressing the problem directly in order to prevent spreading or further contamination in products and buildings. This can be a cleaning operation, but also a control operation by the pest control technician or the disposal of contaminated stocks.
- Addressing the problem in the future. Many preventive measures can be taken.

The matrix in Fig. 14.7 shows how different types of pests can be related to various causes.

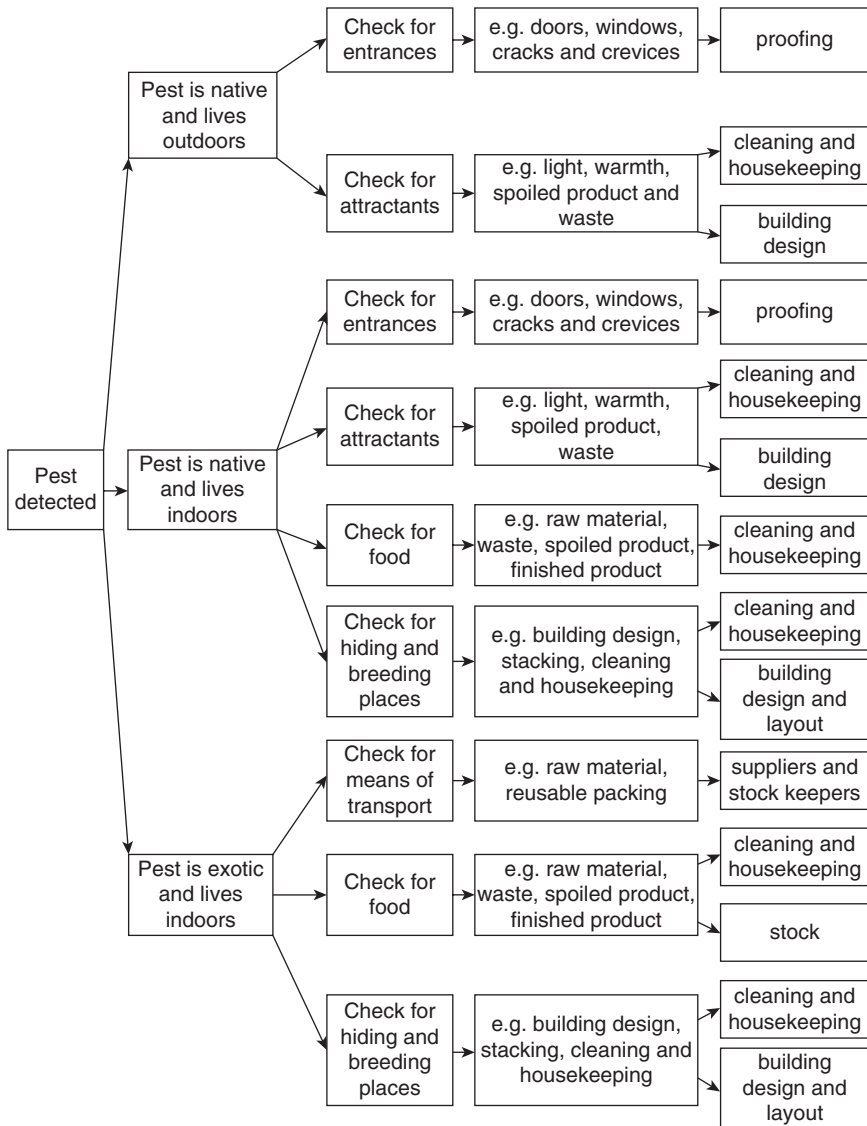
## 14.6 Communication

A good pest control program informs anyone at the factory who is involved with the quick and efficient prevention and control of pests about the state of affairs.

### 14.6.1 Contact persons

The following persons or departments are most likely to be involved in the fight against pests in a food business:

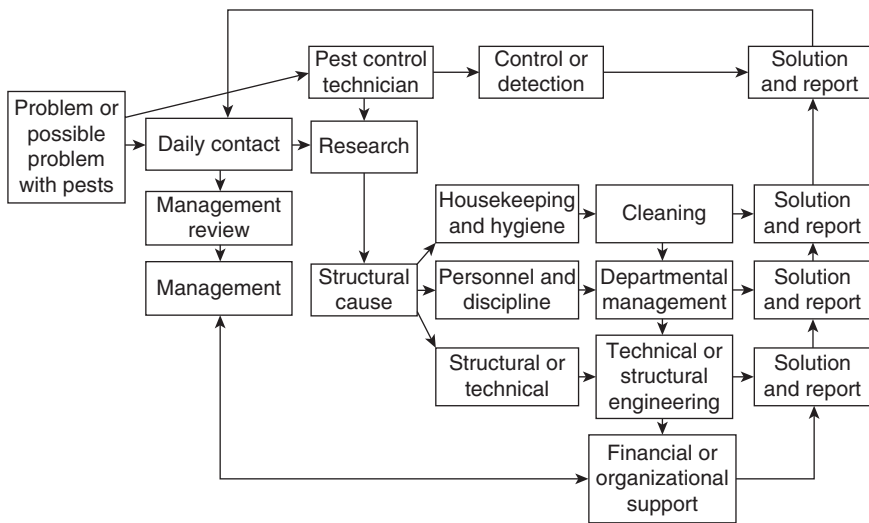
- **Quality department.** The quality department usually provides the daily contacts. Quality departments are also involved in coordinating the pest control program's standards and legal requirements.
- **Management.** Management is not always directly involved in pest control but the management team needs to be completely supportive when it comes to making adequate resources available in order to meet proposed objectives and prevent and solve pest problems.
- **Departmental leadership.** When problems with pests occur in a particular food production department, the immediate supervisor must be informed and kept up to date.
- **Technical department.** In addressing the structural causes of problems with vermin, the technical department is of great importance. This department should always be informed.



**Fig. 14.7** Matrix showing how different types of pests can be related to various causes.

- **Hygiene services.** Good cleaning and the collection and disposal of waste are of great importance in the prevention of pests.

Figure 14.8 shows that problems with pests can usually be resolved by the pest control company in collaboration with the various disciplines. Sometimes, however, support from management is needed for large investments and organizational or disciplinary measures.



**Fig. 14.8** Schedule of the communication of a (possible) pest problem.

### 14.6.2 Feedback

The communication involved within the pest control program is a two-way process. Naturally, it is important that the company knows what needs to be done to prevent problems, but the pest control technician should also be well informed of what is happening. He or she should know if preventive measures are taken or when recommended measures are impossible to implement.

As for all food safety programs, corrective actions should be executed and recorded in response to any non-compliance raised against the pest control program. Feedback must be given on the reports made by the pest control company and this feedback should be as informative as possible. The simple date and sign off of a corrective action is sufficient in most cases; however, more information is sometimes needed, especially in circumstances in which advice cannot be executed. Modified advice might sometimes be necessary.

## 14.7 Maintaining and evaluating the pest control program

Pest control programs should be maintained, and this applies not only to the physical program that consists of the monitoring devices, but also to the administrative program. Pest control programs ‘wear’ because monitoring devices get lost or damaged, and sometimes the requirements of customers and food safety programs change or the company itself expands or renovates.

It is therefore essential that a pest control program is consistently maintained and is evaluated at least once a year.

#### **14.7.1 Maintaining the pest control program**

Pest control programs are periodically inspected by a pest control technician. The technician checks baits or traps for rodents, insect traps and maintains EFCs. To prevent problems with pests it is important that this is carefully and consistently done and that the collected data are correct.

Monitoring devices should remain at the right place (according to the location maps) and should be properly labelled. Irregularities should be addressed immediately, otherwise collected data could lead to incorrect conclusions. In particular:

- Damaged monitoring devices should be repaired or replaced immediately. Failing that, a note should be made in the log.
- Monitoring devices that have disappeared should be replaced immediately. When they contain toxic pesticides, they should be tracked and found.
- Replaced monitoring devices should be placed back in the pest control program (and should be registered on maps and checklists).
- New monitoring devices (even temporary ones) should be added to the program.

It is also important that the monitoring devices are clean, the rodent baits fresh and glue traps for insects still sticky.

#### **14.7.2 Evaluating the program**

Companies and circumstances change constantly. It is therefore important to regularly discuss whether a pest control program still meets the latest requirements and still fits the company and its production processes. The pest control program should therefore be reviewed at least annually with all persons involved. A report of this evaluation should be kept in the log.

During the evaluation the following should be discussed:

- Does the pest control program work?
- Does the program still meet the latest requirements of the food safety program?
- Does the program still meet all legal requirements?
- Are all (known) risks covered by the program?
- Are any unnecessary monitoring devices being used and, if so, can they be removed?
- Is the program (plans, procedures, registration lists, etc.) still up to date?

An evaluation should not be ad hoc, but instead planned in a fixed schedule. It is an important part of the pest control program and all stakeholders should be present.

## **14.8 Conclusion**

Standard pest control programs in general focus mainly on controlling pest problems rather than preventing them. However, dedicated pest control programs in food businesses should do more than that. A good pest control program is based on the principle of IPM and does not just contain information about the use of pesticides and action taken to control pests. It should provide guidance to the management about preventing future problems without the unnecessary use of (toxic) means.

Registration and communication are essential when pests are detected. Management and employees need to know if there are pests present, but is it is even better when they know what to do to prevent problems with pests.

## **14.9 Future trends**

In western Europe the following developments are already under way.

### **14.9.1 Internet**

More and more pest control companies use the Internet to report the results of their work to their customers. Often these reports are still simple word processing documents, but some pest control companies already have comprehensive interactive logs in which all information is presented in real time. The ability to quickly obtain current information on pests in the company allows for a rapid and lasting solution for pest problems.

### **14.9.2 Barcode scanners**

Many pest control companies use barcode scanners to check monitoring devices. A barcode on a mousetrap, for example, then corresponds with a mousetrap on a map or in a checklist.

Barcode scanners ensure that current information is readily available to the food business and that rapid action can be undertaken. Barcode scanners are, however, susceptible to fraud, as it is often possible to operate them manually.

### **14.9.3 Wireless programs**

In companies where mechanical traps are required to catch and detect mice, mousetraps with a transmitter are sometimes used. When a mouse is caught,

a signal is sent to warn the relevant employee via telephone or e-mail. These devices are very sensitive and laborious, so no application of these on a grand scale currently exists. Strict regulation of the use of rodenticides to detect mice and rats can result in the wider use of these sophisticated rodent control systems.

#### **14.9.4 Control and eradication by own employees**

Food safety programs, especially programs from the United States, demand increasingly intensive checks and accurate records. In some cases, monitoring devices (mousetraps) must be checked weekly or even daily. If monitoring devices are not toxic, they may (in principle) be checked by anyone. As a result, these checks are increasingly performed by the food manufacturer's own staff. The deployment of their own staff, along with a qualified pest control technician, offers many advantages. The knowledge and the level of training are guaranteed by the external experts, while the use of the food manufacturer's own people increases the internal commitment.



## Pest control of stored food products: insects and mites

C. H. Bell, Food and Environment Research Agency, UK

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**Abstract:** This chapter covers the range of methods used to control arthropods causing problems after harvest and during storage of food commodities and agricultural products. Control procedures in use may be divided into measures based on physical, chemical or biological aspects. Methods based on extreme temperatures, atmosphere modification, physical barriers, impaction, inert dusts, irradiation, UV traps, attractants, natural and synthetic chemical pesticides, fumigants, growth regulators, pathogens, parasites or predators are described and threats to the continued successful control of pests are discussed.

**Key words:** stored products, beetles, moths, mites, pest detection, pest management.

### 15.1 Introduction

Insects occur at every point along the chain of food production from the open field or greenhouse environment to larders and pantries in domestic premises. Their presence causes concern not only because of their appearance and the direct spoilage they cause to food products, but also because of the microbiological contaminants and pathogens they may carry, and because of possible allergenic reactions that their exuviae and frass may generate. Infestation of a single species of bruchid (*Callosobruchus maculatus* (F.)) has been estimated to cause losses of 4% of the stored cowpea crop in Nigeria each year (Lale and Mustapha, 2000) while weight losses caused by stored product pests of over 20% have often been reported for maize stored in developing countries (Krall, 1987; Giga *et al.*, 1991; Phillips and Throne, 2010). Clearly direct losses are highest in tropical climates where conditions are optimal for rapid population increase but even in the cooler climates of Western developed nations very low tolerances for arthropod presence result in high losses during trading of food commodities. The cost of transport and treatment of bulk produce arriving

by road or rail can be 10–20% of the load value (Hagstrum and Subramanyam, 2000).

The association of insect pests with diseases and contaminants is a field that has received little attention over the years, although the health implications of insect infestation have long been realised (Busvine, 1964). Besides the risk of insects acting as vectors for pathogens, links between allergies and stored product infestations have been documented in a number of situations (Herling *et al.*, 1995; Armentia *et al.*, 1997). Mites in particular have long been associated with various skin allergies, asthma and systemic anaphylaxis (Dekker, 1928; Sporik *et al.*, 1990; Matsumoto *et al.*, 1996; Chambers, 2003; Stejskal and Hubert, 2006). Although mites occur widely in domestic premises, it is only relatively recently that firm evidence has been obtained for their physical presence in food (Chambers *et al.*, 1999, and references therein). Although the proportion of occasions on which the ingestion of storage mites or their faeces affects human health may be small, the presence of mites is clearly not consistent with increasing demands from customers for food of high quality, free from health risks. There has been increasing difficulty in achieving effective control of insects and mites with conventional pesticides and effective alternative approaches are needed urgently.

The occurrence of insects and mites in the food industry continues to be a major problem. In many countries food processors and distributors are under legal obligation to combat infestation to the point where no insects can be detected towards the end of the food chain. A wide range of control methods in use or at an advanced stage of investigation are described below.

## 15.2 The spread of pests

The association of insects with man's attempts to store food reaches back into early history. Evidence of several species currently associated with grain and meals has been found in the remains of offerings left in the tombs of ancient Egypt to accompany the departed on his or her journey, and stored product beetle remains date back to Roman times in Britain (Howe, 1991). Most species that have risen to significant pest status have been traced to natural habitats such as bird and animal nests, forest litter, dried vegetable matter and dried animal carcasses. Over the years well over 100 species have had a strong association with stored food and Table 15.1 lists a selection of the more commonly encountered pests and the foods they prefer.

With the advent of increased storage of food for longer periods and the establishment of international trade, many species of tropical origin have become established in food handling premises in temperate zones. Here storage conditions in particular locations can be and are changed by mould

**Table 15.1** Arthropod pests and their occurrence on foods

Species	Common name	Food products attacked
Acarina (mites)		
<i>Acarus siro</i> (L.)	Flour mite	Flour, grain, meals
<i>Acarus farris</i> (Oedemans)	–	Cereals
<i>Carpoglyphus lactis</i> (L.)	Dried fruit mite	Dried fruit, jams
<i>Lepidoglyphus destructor</i> (Schrank)	Cosmopolitan food mite	Cereals, flour, oilseeds
<i>Tyrophagus longior</i> (Gervais)	Grainstack mite	Grain, brans
<i>Tyrophagus putrescentiae</i> (Schrank)	Mould or cheese mite	Herbs, seeds, meals, dairy products, oilseeds
Dictyoptera (cockroaches)		
<i>Blatta orientalis</i> L.	Oriental cockroach	Food residues in kitchens, food processing facilities
<i>Blattella germanica</i> (L.)	German cockroach	
<i>Periplaneta americana</i> (L.)	American cockroach	
<i>Periplaneta australasiae</i> (F.)	Australian cockroach	
Psocoptera (book lice, psocids)		
<i>Lepinotus patruelis</i> Pearman	Black domestic psocid	Opened packets in larders
<i>Liposcelis bostrychophila</i> Badonnel	Stored product psocid	Larders, pantries, grain
Coleoptera: Anobiidae		
<i>Lasioderma serricorne</i> (F.)	Cigarette beetle	Herbs, cocoa, soya, cereals
<i>Stegobium paniceum</i> (L.)	Drug store, bread or biscuit beetle	Flours, meals, powders
Coleoptera: Anthribidae		
<i>Araecerus fasciculatus</i> (DeGeer)	Coffee bean weevil	Coffee and cocoa beans
Coleoptera: Bostrichidae		
<i>Prostephanus truncatus</i> (Horn)	Larger grain borer	Maize
<i>Rhyzopertha dominica</i> (F.)	Lesser grain borer	Cereal grains
Coleoptera: Bruchidae		
<i>Acanthoscelides obtectus</i> (Say)	American seed beetle	Beans
<i>Bruchidius atrolineatus</i> (Pic)	–	Cowpeas
<i>Bruchus ervi</i> Froelich	Mediterranean pulse beetle	Lentils, pulses
<i>B. lentis</i> Froelich	Pulse beetle	Beans, pulses, lentils
<i>B. pisorum</i> (L.)	Pea weevil	Peas, beans
<i>B. rufimanus</i> Boheman	Bean beetle	Beans
<i>Callosobruchus chinensis</i> (L.)	Adzuki bean weevil	Various beans and peas
<i>C. maculatus</i> (F.)	Cowpea weevil	Cowpea, beans, groundnuts
<i>Caryeden serratus</i> (Olivier)	Groundnut seed weevil	Pods, pulses, groundnuts

**Table 15.1** *Continued*

Species	Common name	Food products attacked
<i>Zabrotes subfasciatus</i> (Boheman)	Mexican bean weevil	Beans, tropical legumes
Coleoptera: Cleridae		
<i>Necrobia ruficollis</i> (F.)	Red shouldered ham beetle	Dried fish, meat and dairy products, copra, cassava, dried fruit, cocoa
<i>N. rufipes</i> (Degeer)	Copra beetle, red legged ham beetle	
Coleoptera: Cucujidae		
<i>Cryptolestes ferrugineus</i> (Stephens)	Rusty grain beetle	Cereals, dried fruit, cocoa
<i>C. pusillus</i> (Schoenherr)	Flat grain beetle	Cereals, various meals
<i>C. turcicus</i> (Grouvelle)	Turkish grain beetle	Cereal products, flour
Coleoptera: Curculionidae		
<i>Sitophilus granarius</i> (L.)	Granary or grain weevil	Wheat, barley
<i>S. oryzae</i> (L.)	Rice weevil	Cereal grains
<i>S. zeamais</i> Motschulsky	Maize weevil	Cereal grains
Coleoptera: Dermestidae		
<i>Attagenus unicolor</i> (Brahm)	Black carpet beetle	Cereal products, fish meal Bacon, sausage, dried fish, ham, cheese, cocoa, bone meal, dog biscuits, etc.
<i>Dermestes haemorrhoidalis</i> Kuster,	Black larder beetle	
<i>D. lardarius</i> L.	Larder beetle	
<i>D. maculatus</i> Degeer	Hide beetle	
<i>Trogoderma glabrum</i> Herbst	–	
<i>T. granarium</i> Everts	Khapra beetle	Cereal products, pet food
<i>T. variabile</i> Ballion	–	Grain and cereal products Grain
Coleoptera: Nitidulidae		
<i>Carpophilus dimidiatus</i> F.	Corn sap beetle	Dried fruit, cocoa, copra
<i>C. hemipterus</i> (L.)	Dried fruit beetle	Dried fruit and related products
Coleoptera: Ptinidae		
<i>Ptinus fur</i> (L.)	White marked spider beetle	Cereal residues
<i>P. tectus</i> Boieldieu	Australian spider beetle	Cereal residues
Coleoptera: Sylvanidae		
<i>Ahasverus adveni</i> (Waltl)	Foreign grain beetle	Grain, copra, oilseeds
<i>Cathartus quadricollis</i> Guer	Square-necked grain beetle	Cereals, dried fruit, cocoa
<i>Oryzaephilus mercator</i> (Fauvel)	Merchant grain beetle	Oilseeds, dried fruit, cocoa
<i>O. surinamensis</i> (L.)	Saw-toothed grain beetle	Cereals, dried fruit, nuts and oilseeds

*(Continued)*

**Table 15.1** *Continued*

Species	Common name	Food products attacked
Coleoptera: Tenebrionidae		
<i>Cynaues angustus</i> (LeConte)	Larger black flour beetle	Grain, meals
<i>Gnatocerus cornutus</i> (F.)	Broad-horned flour beetle	Flour, cereal products
<i>G. maxillosus</i> (F.)	Slender-horned flour beetle	Flour, pulses
<i>Latheticus oryzae</i> Waterhouse	Long-headed flour beetle	Grains, groundnuts, cassava
<i>Tenebrio molitor</i> L.	Yellow mealworm	Cereal and other residues
<i>T. obscurus</i> F.	Dark mealworm	Cereal residues etc
<i>Tribolium castaneum</i> (Herbst)	Rust-red flour beetle	Cereal products, oilseeds, cocoa, nuts, dried fruit, most stored products
<i>T. confusum</i> J. du Val	Confused flour beetle	
Coleoptera: Trogossitidae		
<i>Tenebroides mauritanicus</i> (L.)	Cadelle	Cereals, seeds, nuts, dried fruit
Lepidoptera: Gelechiidae		
<i>Sitotroga cerealella</i> (Olivier)	Angoumois grain moth	Cereal grains
Lepidoptera: Oecophoridae		
<i>Hofmannophila pseudospretella</i> (Stainton)	Brown house moth	Opened packets and food residues in kitchens
Lepidoptera: Pyralidae		
<i>Corcyra cephalonica</i> (Stainton)	Rice moth	Cereals, dried fruit, cocoa
<i>Ephestia cautella</i> (Walker)	Tropical warehouse moth	Cereals, dried fruit, nuts etc.
<i>E. elutella</i> (Huebner)	Warehouse moth	Cereals, cocoa
<i>E. figulilella</i> Gregson	Raisin or fig moth	Dried fruit
<i>E. kuehniella</i> Zeller	Mediterranean flour moth	Cereals, flour
<i>Paralipsa gularis</i> (Zeller)	Stored nut moth	Nuts, cocoa, dried fruit
<i>Plodia interpunctella</i> (Huebner)	Indian meal moth	Nuts, dried fruit, cereals, oilseeds, cocoa, meals, etc.

and insect activity to simulate those in the tropics. Hence many species have become truly cosmopolitan in distribution. A tropical origin is reflected in a high-temperature optimum for development, but in addition many species possess a cold tolerant stage, usually the adult or mature larva. This is an important ingredient for survival in the temperate environment when the environmental buffering effect of the stored commodity is lost because of the periodic emptying of the store. Native species normally have life cycles

linked to the seasonal cycle and pass the winter in a state of diapause, the insect equivalent of hibernation. The occurrence of cold tolerance in tropical species may seem surprising at first but in fact cold tolerance is often linked to a tolerance of high temperatures also. An ability to survive short periods at high temperatures is a necessary survival mechanism for beetles living in the tropics where mid-day temperatures often exceed 40°C. Conversely, tolerance to short heat exposures is often found in cold tolerant stages such as the overwintering larvae of warehouse moths (Bell, 1983).

The spread of stored product pests is continuing today. Until the 1970s, the greater grain borer *Prostephanus truncatus* (Horn) was a species more or less confined to Central America. In the 1980s it appeared as a major pest in Africa, and has since spread across the continent and causing heavy losses to maize crops. On another front Howe (1991) tracks the arrival of a succession of ptinid beetle pests of flour mills from 1830 to 1939 in parallel with the growth of international trade. The same period has seen the worldwide establishment of the Mediterranean flour moth *Ephesia kuehniella* Zeller in flour mills and subsequently we have seen the replacement of the granary weevil *Sitophilus granarius* (L.) by the saw-toothed grain beetle *Oryzaephilus surinamensis* (L.) as the principal pest of stored grain in Western Europe. Undoubtedly, the ability of beetles from warm climates to overwinter at higher latitudes in refuges in the fabric of stores has been a major ingredient in their becoming established as major pests throughout the world's food supplies.

## 15.3 Physical control of pests

Logically, the use of physical control methods is the primary route to follow to avoid and combat pest control problems. Physical control remains one of the most actively researched fields in the quest to devise new pest control strategies.

### 15.3.1 Aeration

The use of aeration to provide moderately low temperatures to control infestations by storage pests has long been recommended (Burgess and Burrell, 1964). Insect pest development is brought to a halt between 10 and 20°C, depending on the species, although several mite species are known to continue development down to 5°C. Most of the immature stages of stored product pests die off if grain is held at less than 5°C for several weeks though adults may survive.

Aeration is used widely in temperate climates for the cooling of bulk commodities such as grain. It is engineered by a fan fitted to a purpose-designed ducting system. This supplies an air flow to the base of a silo or to evenly spaced channels under the floor of a grain store which are covered

by fine mesh metal panels to prevent ingress of grain. In the absence of a ventilated floor, reinforced perforated ducts can be laid on the floor prior to the arrival of the grain and manifolded to a fan-driven air flow. It is often considered that a secondary use for aeration is for grain drying or conditioning. However, the aeration flow rates to achieve any significant change in grain moisture content need to be at least an order of magnitude greater than for cooling, and usually the fans installed in grain stores are unable to generate this volume of air movement. For any effective result the air passing through the system needs to be cooler and drier than the commodity and so some kind of fan control needs to be employed to shut down air flows in warm or very wet weather.

Aeration can readily be practised in warmer climates or in the summer by utilising the time of day when cool temperatures prevail (Armitage, 1987; Lasseran and Fleurat-Lessard, 1991) or coupling the system to a refrigeration unit (Brunner, 1987; Mason *et al.*, 1997). Aeration is a part of many grain pest management programmes and plays a most important role in preventive control measures at a cost highly competitive with other disinfestation processes (Armitage *et al.*, 1991).

### 15.3.2 Cold

Apart from the use of aeration systems for bulk commodities described above, cold treatments are widely used as part of integrated pest management (IPM) systems for stored products (including grains, cereals, oilseeds and seeds), especially in countries with low ambient temperatures after harvest, for example in Canada, but is also used in the dried fruit industry where cold storage warehouses are part of a storage system. Cold storage is also used for fresh fruit and other perishable commodities.

Most insects require only a short exposure at very low temperatures ( $-10^{\circ}\text{C}$  or below) to ensure control (Chauvin and Vannier, 1991; Fields, 1992). The stage of development of the pest is a factor in its cold resistance: eggs are more sensitive, and adults or larvae are the most cold tolerant (Banks and Fields, 1995). Furthermore, some species of insects have the ability to acclimatise to cold and may become tolerant to otherwise lethal cold temperatures. For this reason, rapid cooling from harvest temperatures to cold temperatures should be part of any storage strategy to prevent cold acclimatisation and improve insect control.

The intense periods of winter cold have long been used by millers and warehouse keepers in Canada and the northern USA for a 'freeze out' of pests (Worden, 1987) and there is seldom a need for chemical control methods in the first few months after treatment. Cold can also be used as a spot treatment by the injection of liquid nitrogen into confined spaces such as wall voids. However, insulation in walls can affect cold distribution, causing warm spots in walls. Interior surfaces can be stained and warping of wooden structural components is possible.

Cold storage is widely used for post-harvest treatments of perishable commodities. Sub-zero temperatures have a rapid effect on insects but it is not necessary for temperatures to be this low to be of use for pest control. Insects may be lethally injured by cold shock even though their body fluids do not freeze (Lee, 1991). Quick freezing at temperatures below  $-10^{\circ}\text{C}$  is really only suitable for fruit pulp or slices on route for processing into juice, as extensive damage occurs to the unprocessed treated commodity (Gould, 1994). Usually the exposure to cold is for a limited period, as, for example, the holding of fruit for 10–22 days at  $-1^{\circ}\text{C}$  to  $+2^{\circ}\text{C}$  to kill tephritid fruit flies on citrus fruit, apples, pears, grapes, stone fruit, carambola, lychees, loquats and kiwifruit (Gould, 1994). Potential quarantine treatments based on cold exposure have also been investigated for codling moth *Cydia pomonella* (L.) (Moffitt and Burditt, 1989; Hansen *et al.*, 2007) and oriental fruit moth *Grapholitha molesta* (Busck) (Yokoyama and Miller, 1989), but high tolerance of larval stages, particularly those in diapause, limits implementation of the technique.

For commercial treatment of perishable commodities, cold treatment is carried out in transit in export containers or by using land-based facilities, and precise records of the temperature and duration of exposure are required to show compliance with phytosanitary treatment specifications in order for the disinfestation treatment to be acceptable to the receiver. Exposure times and temperatures are linked to the pest but need to be chosen after evaluation of effects on the fruit being treated. Many tropical and sub-tropical fruits are susceptible to cold, but chilling injury can be reduced if the commodity is conditioned at moderate temperatures prior to exposure to cold (Houck *et al.*, 1990), or if there are interruptions during the low-temperature exposure (Paull and McDonald, 1994) though treatment efficacy may be affected. Details of cold exposures required for effective control of fruit fly species are given in Table 15.2, based on information collected for the USDA-APHIS-PPQ Treatment Manual (Gould, 1994).

The effects of cold on insect and mite pests of durable products were reviewed by Fields (1992). Fields and White (1997) equate the rate of population development, rather than just the ability to survive cold temperatures, with the pest status of stored-product insects in Canada. The threshold for population growth for several major insect pests lies between  $14$  and  $20^{\circ}\text{C}$  (Beckett, 2011). Below  $10^{\circ}\text{C}$  insect reproduction ceases and population levels of most pests decline and will eventually die out. However, even at  $4^{\circ}\text{C}$  adults of most species can survive for many months. Immature stages of species of tropical origin, such as *Sitophilus oryzae* (L.), *S. zeamais* Motschulsky, *Tenebroides mauritanicus* (L.) and *Lasioderma serricorne* (F.) tend to be cold sensitive, although those of some important pests including *S. granarius*, *Cryptolestes* spp., bruchids, mites and some Lepidoptera are quite tolerant (Armitage, 1987; Lasseran and Fleurat-Lessard, 1991; Fields, 1992). In consequence, cooling typically requires very long holding times to be effective.



**Table 15.2** USDA-APHIS-PPQ cold treatment times for different species of fruit fly (after Gould, 1994)

Species/group	Cold treatment
<i>Ceratitis capitata</i> (Wiedemann)	10 days at 0°C or below 11 days at 0.55°C or below 12 days at 1.11°C or below 14 days at 1.66°C or below 16 days at 2.22°C or below
<i>Anastrepha ludens</i> (Loew)	18 days at 0.55°C or below 20 days at 1.11°C or below 22 days at 1.66°C or below
Other species of <i>Anastrepha</i>	11 days at 0°C or below 13 days at 0.55°C or below 15 days at 1.11°C or below 17 days at 1.66°C or below
<i>Bactrocera tryoni</i> (Froggatt)	13 days at 0°C or below 14 days at 0.55°C or below 18 days at 1.11°C or below 20 days at 1.66°C or below 22 days at 2.22°C or below

Cold treatments are used as part of IPM systems and for disinfestation or management of grain pests in stored grain or grain storage structures (Fields and Muir, 1995; Banks and Fields, 1995). Besides aeration (see Section 15.3.1), cooling can be achieved by turning the grain through a conveyer, transferring grain from one bin to another in cold weather, and leaving it outside if possible for a few days before returning it to storage. As mentioned in the previous section, where ambient conditions are unfavourable for normal aeration, i.e. high temperature or humidity, air dehumidified and chilled using a refrigeration unit may be used for the aeration. Many grain silos in the Mediterranean and subtropical regions use this process (Brunner, 1987). The strategy is to reduce the temperature of the grain within a few days after harvest to below the development temperature threshold of the main insect pests. A single refrigeration unit is used for several bins in a silo system, each bin being refrigerated in turn for a few days. The equipment is, however, energy consuming and can be expensive.

Cold storage has been extensively used in the dried fruit industry, though very low temperatures are unsuitable for storage of dried vine fruit because of the resulting crystallisation of sugars. It is used for prunes, dates and dried pears, and is appropriate for nuts and beverage crops. Cooling to very low temperatures (−10 to −18°C) is an established system for the disinfestation of dates, a 10.5 hour exposure to −10°C, or 2.25 hour exposure to −18°C, killing all stages of the relevant insect pests (Donahaye *et al.*, 1991). It is most effective when combined with a brief exposure to low pressure or low

(<3%) oxygen, which causes insects to leave the centre of the fruit (Donahaye *et al.*, 1992), and thus become more susceptible to the cold treatment.

All common stored product insect pests can be controlled in food media exposed for 2 weeks to temperatures at or below  $-18^{\circ}\text{C}$ , i.e. in an efficient freezer. This type of treatment is used preventatively for the disinfestation of high-value products, such as special seed stocks, and organically grown rice, in some countries. This technique is efficient but only practicable for small quantities in batches. It is important to note that the temperature to control the pests must be reached throughout the product to be protected and that many commodities are poor thermal conductors and provide some protection against the cold. It cannot be assumed that ambient temperature and commodity temperature are the same and accurate temperature monitoring systems are required.

### 15.3.3 Controlled atmospheres (CA)

Treatment with controlled atmospheres (CA) based on replacement of air with carbon dioxide ( $\text{CO}_2$ ) or nitrogen offers an alternative to fumigation for insect and mite control in all durable commodities. CAs have also long been in use on fresh fruit and vegetables but mainly for the purpose of delaying ripening and ageing, which involve much higher oxygen levels and much lower  $\text{CO}_2$  levels than those required for insect control. For effective control of most insects, atmospheres need to contain less than 1% oxygen or a minimum of 40–60%  $\text{CO}_2$  while for mites a slightly higher oxygen level of 2% retains efficacy, although holding oxygen levels below 4% in air will prevent a population increase of most species (Conyers and Bell, 2007). CAs with high levels of  $\text{CO}_2$  or less than 1% oxygen are able to halt the growth of fungal pests but are unable to destroy them. Work on the effect of CAs on different insect pests of perishable commodities was reviewed by Carpenter and Potter (1994) who carried out the first commercial CA quarantine treatment in the export of asparagus from the USA to Japan, featuring a 4.5 day exposure to 60%  $\text{CO}_2$  followed by transport at  $0-1^{\circ}\text{C}$ .

CAs require a long time (weeks rather than days) for effective action and are unlikely to be used for disinfestation where fast turn-around is necessary, unless combined with other factors such as high pressure or raised temperature. The technology may require registration or other regulatory approval in some countries. The times required for control of various storage pests are listed in Table 15.3.

Low oxygen atmospheres can be generated by the physical separation of oxygen and nitrogen from air, by burning a hydrocarbon fuel such as propane, or by obtaining nitrogen gas from cryogenic tanks or pressurised gas cylinders. The use of bulk gas supplies is the most expensive option and is little used. Two systems exist for the separation of nitrogen from air,

**Table 15.3** Exposures (days) required for kill of storage insects under two controlled atmospheres (after Bell, 1996)

Species and stages	60–95% CO <sub>2</sub>		<1% O <sub>2</sub>		
	15–20 °C	25–30 °C	15–20 °C	25–30 °C	35–40 °C
<i>Acarus siro</i> , all stages	6–14	–	7	–	1
<i>Cryptolestes ferrugineus</i> , adults	7	4	6–10	2	–
<i>Ephestia cautella</i> , eggs & larvae	7	5	5–6	2	–
<i>E. elutella</i> , diapausing larvae	14	–	>28	–	–
<i>Lasioderma serricorne</i> , all stages	–	6	9	6	1
<i>Liposcelis bostrychophila</i> , all stages	8–14	–	–	2	1
<i>Oryzaephilus surinamensis</i> , adults	5	3	4–10	–	–
<i>Rhyzopertha dominica</i> , all stages	28	–	>28	–	–
<i>Sitophilus oryzae</i> , all stages	28	>18	>28	>18	–
<i>S. granarius</i> , all stages	42–56	>9	>49	>14	–
<i>Tribolium castaneum</i> , adults	6	3	4–7	2	1
<i>Trogoderma granarium</i> , larvae in diapause	>18	>17	–	>14	–
<i>Tyrophagus longior</i> (Gervais), all stages	14	–	14	–	–

pressure swing adsorption (PSA) and membrane filtration. PSA operates by passing compressed air through two beds of molecular-sieve coke. The nitrogen and oxygen are separated due to their different rates of adsorption with the nitrogen passing through the bed and into a holding tank. The two beds work alternately with one pressurised with incoming air while the other is returned to atmospheric pressure, releasing the more strongly sorbed oxygen and other gases to waste. The second system is based on filtration of compressed air through a vessel containing thousands of semipermeable membrane tubes which differentiate between oxygen and nitrogen, oxygen permeating through the membrane to the space between the tubes while nitrogen is retained.

Carbon dioxide atmospheres typically are applied at about 60% CO<sub>2</sub> in air, using supplies of liquid CO<sub>2</sub> and a vaporiser. At this level there is about 8% oxygen present, and although this amount of oxygen would be able to support the development of most stored product pests indefinitely, the CO<sub>2</sub> atmosphere is lethal to pests provided that the exposure can be sufficiently

prolonged. CO<sub>2</sub> thus has a direct toxic effect on insect pests (Bell *et al.*, 1980) and does not act only as an inert gas that reduces the oxygen level to below that supporting life. Data on exposure times for control are available for many species and stages of stored product pests under particular sets of conditions (Annis, 1987; Bell, 1996; UNEP, 2011). Most species are completely controlled by exposures of 2–3 weeks at 25–30°C. As an extreme case, larvae of *Trogoderma granarium* Everts in diapause require exposures longer than 17 days at 30°C, with CO<sub>2</sub> levels at or above 60% in air (Spratt *et al.*, 1985).

Structures for use with CAs must be well sealed to achieve and maintain effective gas levels and keep gas usage to within economically acceptable bounds (Mann *et al.*, 1997). Silo bins that were sealed to a standard suitable for recirculatory fumigation with methyl bromide are typically suitable for CA use. The use of a continuous flow of CA, such as that provided by combustion of propane, can allow somewhat less gas-tight enclosures to be treated successfully (Bell *et al.*, 1993, 1997). Application of CA may be constrained by the cost of the hydrocarbon fuel, CO<sub>2</sub> or nitrogen required, particularly in developing countries. However, the technology of generating nitrogen from air on-site is progressing rapidly and competitively priced, efficient systems are now available. Propane or liquefied petroleum gas (LPG) burners offer one of the cheapest methods of continuously generating a low oxygen atmosphere on site as established by tests in the USA, France and the UK. Loaded grain bins of over 1000 tonnes capacity have been held under a less than 1% oxygen atmosphere for treatment periods long enough to kill all pests (Fleurat-Lessard and Le Torc'h, 1987; Bell *et al.*, 1997).

The effective use of CO<sub>2</sub> for grain storage was developed principally in Australia and the USA, although Australia, for preference, mainly uses the fumigant phosphine to treat bulk grain. However, CO<sub>2</sub> is being used for stored rice and other bagged commodities in some South East Asian countries where bagged grain is stored in warehouses. CO<sub>2</sub>-based CA systems are used on a large scale in Indonesia for long term storage of bagged milled rice stocks (Nataredja and Hodges, 1990; Sukprakarn *et al.*, 1990). Until recently, use of CO<sub>2</sub>-based atmospheres was preferred over N<sub>2</sub>-based ones for bulk grain for various technical reasons. Recent developments in the on-site generation of N<sub>2</sub>-based atmospheres have altered this situation. N<sub>2</sub>-based controlled atmospheres are in commercial use in Australia at an export grain terminal in bins originally designed and equipped for methyl bromide treatments (Cassells *et al.*, 1994).

In the dried fruit and nut industry the improved quality retention of many products held under CA makes the technique an attractive proposition for pest control. Treatment of almonds in silos with CA has been successfully demonstrated under full-scale commercial conditions (Soderstrom *et al.*, 1984). Use of CO<sub>2</sub> as a control procedure has also been successfully tested for sultanias in cartons in stacks (Tarr *et al.*, 1994), and in export freight containers (Banks *et al.*, 1993b). Improvements in on-site generation of

nitrogen (Navarro and Donahaye, 1990; Bell *et al.*, 1993; Banks and Annis, 1997) should encourage further studies on the use of low oxygen atmospheres for these commodities.

High-pressure CO<sub>2</sub> (above 20 bar) can potentially provide a very rapid disinfestation system of commodities (Nakakita and Kawashima, 1994; Ulrichs, 1994). CO<sub>2</sub> at about 25 bar pressure is in limited use in Germany to treat beverages, nuts and spices (Prozell *et al.*, 1997), controlling all stages and species of pest insects in less than 3 hours. The high construction and operating costs of pressure chambers require investment capital to be available but several industries have brought the technique into use. The rate at which the pressure can be released affects the efficacy of action (Nakakita and Kawashima, 1994; Ulrichs, 1994), but in practice there are physical constraints on the rate at which pressures can be manipulated.

#### 15.3.4 Exclusion and packaging

Packaging of finished food products is a vital aspect of infestation prevention. The package should be designed to protect the product from the point of manufacture to the time it is consumed, an interval which can be as long as several years (Mullen and Pederson, 2000). Insect pests with a known ability to penetrate paper and polythene packaging include the beetles *Rhyzopertha dominica* (F.), *Lasioderma serricorne* and *Stegobium paniceum* (L.) and larvae of the moths *Plodia interpunctella* (Hubner) and *Corcyra cephalonica* (Stainton). Many other stored product pests are opportunistic in entering packages through tiny gaps and imperfections in the seal. Newly hatched moth larvae can enter gaps of less than 0.2 mm while immature mites need a gap of only 0.05 mm (Athanasios *et al.*, 2011; Bell, 2011). Packaging needs to be designed to avoid as far as possible folds and glue seals need to avoid channels and over-wraps. Use of materials acting as a barrier to the escape of food volatiles or odours is helping to minimise pest attraction. Alternatively, the use of a repellent such as methyl salicylate can be incorporated in the packaging. Another option is packaging under modified atmospheres. The packaging of fresh fruit and vegetables using polyfilms or coatings made from wax or cellulose-based compounds that are impermeable to atmospheric gases offers the option of self-modification of the atmosphere immediately surrounding the commodity to levels preventing pest development (Hallman *et al.*, 1994). Shrink wrapping enhances the ability for such an atmosphere to develop. This approach closely resembles the principle of hermetic storage used for storage of other crops (Sabio *et al.*, 2000; Navarro *et al.*, 2001).

#### 15.3.5 Heat

Heat treatment technologies provide for crops and stored products the prospect of rapid elimination of pests, a facility offered by only a few other

techniques such as fumigation with methyl bromide or other fast-acting fumigants. Commodities need to be heated to temperatures sufficiently high to kill the pests present and then rapidly cooled to avoid damage to heat-sensitive products. On perishable crops two types of heated air treatments are practised, vapour heat and forced hot air. Vapour heat was the first to be used and applied hot air saturated with water to the fruit, transferring heat by condensation (Armstrong, 1994). Vapour heat treatments feature a rapid heating phase from ambient followed by a more gradual increase to the critical end point temperatures of 43–57°C, depending on commodity and pest sensitivity. More recently forced hot air at a relative humidity (RH) of less than 90% (usually less than 60%) has been introduced to avoid heat transfer by water condensation, which causes damage in certain fruit (Hoa *et al.*, 2006).

For durable stored products target temperatures can be much higher (up to 70°C), and humidity needs to be carefully controlled to prevent moisture content changes during both heating and cooling operations. The treatment time required is strongly dependent on the temperature reached and experienced by the target pest. If the buffering effect of the food commodity is removed insects are killed within a few minutes above 55°C (Table 15.4).

For fresh fruit and vegetables, hot water dipping is another heat application method. Hot water is an excellent medium for heat transfer and has long been used to reduce pathogens on fruit (Armstrong, 1994). The adverse effects on fruit may be improved by hydrocooling fruit after dipping but the consequence of effectively shortening the treatment exposure to high temperature on treatment efficacy against insects needs consideration if hot water dipping is being used alone rather than in combination with chemicals (Sharp, 1994).

Stored product pest insects (all stages) can be eradicated in approximately 1 minute if they are exposed within the commodity to a temperature of 65°C. This high-speed action allows design of high-throughput plants, such as those based on spouted or fluid beds (Fleurat-Lessard, 1984; Thorpe

**Table 15.4** Response of insect pests to high temperatures experienced by developmental stages (modified after Banks and Fields, 1995, and Burks *et al.*, 2000)

Temperature range (°C)	Effect on insects
25–32	Optimum for development
30–36	Maximum temperature for reproduction of most species
36–42	Populations die out, mobile insects seek cooler zones
42–50	Death within a day
50–60	Death within an hour
Above 60	Death within a minute

*et al.*, 1984; Claflin *et al.*, 1986). Pilot and laboratory studies, reviewed by Sutherland *et al.* (1987) and Banks and Fields (1995), have typically used heated air at 90°C or above, as a heat transfer medium into the grain with the objective of heating the grain briefly to above 65°C. Such exposures cause no detrimental effect on the end use qualities of treated cereals at the levels of heating required to eliminate insect pests. These include breadmaking quality of wheat, rice quality and malting quality of barley (Fleurat-Lessard, 1985; Sutherland *et al.*, 1987). However, the margin of error is small and only slightly excessive treatment can cause some adverse effects (Fleurat-Lessard and Fuzeau, 1991). Fluid-bed heating systems for bulk grain have been developed to a commercial prototype stage, with treatment rates of up to 150 t h<sup>-1</sup> (Thorpe *et al.*, 1984; Sutherland *et al.*, 1987), but installation of large-scale heat treatment facilities has not been widely adopted because of the high capital investment needed. There are currently no installations which meet the handling speeds of large modern grain terminals, often 500 t h<sup>-1</sup> or more on one belt.

The potential for rapid heating of grain by microwaves, radiofrequency radiation or infrared radiation has long been recognised (Boulanger *et al.*, 1969; Nelson, 1972). Recent tests indicate that selective heating of insects infesting stored grain increases non-linearly at frequencies above 10.6 GHz and that a frequency of 28 GHz is close to the optimum for enhanced selective heating of maize weevils inside grains (Halverson *et al.*, 1997). Equipment has been refined to permit dynamic processing at a rate of 24 t h<sup>-1</sup> (Halverson *et al.*, 2000) but much further development is needed to increase throughput rates to those at export terminals.

Brief heat treatments also have potential to disinfest cocoa, coffee and some dried fruit and nuts. Techniques need to be researched carefully before adoption to determine effects on quality parameters of the treated product concerned. It is already known that high-temperature storage or treatment of many dried fruit and nuts can lead to detrimental colour change or rancidity.

Heating above 50°C (122°F) for 20–30 h has been used to control insects in flour mills for over 100 years (Heaps and Black, 1994). It is increasingly used by a number of major food processors as the mainstay of their pest control programme following the withdrawal of the fumigant methyl bromide under the Montreal Protocol (UNEP, 2011). Food plants that can be successfully heat-treated rarely require fumigation. A variety of equipment is available to supply conductive or convective heating for structures such as floor mats, wraps and fan-powered convective heaters which offer black heat sources to reduce the risk of dust explosions (Bartlett *et al.*, 2005; Beckett *et al.*, 2007).

Heating can provide an alternative treatment method to using chemicals but also can synergise other treatments. For fumigants and controlled atmospheres it does this in three ways: by increasing the diffusion and



distribution of gases and hence their powers of penetration, by reducing physical sorption on the commodity and by increasing the toxicity or level of stress to target pests. Heat is particularly effective in increasing the efficacy of control using CO<sub>2</sub>.

### 15.3.6 Impaction

Many situations in which agricultural products are mechanically conveyed during food processing offer the opportunity for control of insects by shock, abrasion and impaction. The principle was developed over 70 years ago for use in the flour milling industry (Cotton and Frankenfeld, 1942) and machines such as the Entoleter became a routine fixture in flour mills. In the Entoleter, flour falls between two rapidly spinning discs. Centrifugal force pushes the flour to the edges of the discs where it impacts a row of steel pegs mounted on the rims, and is thrown against the outer steel casing before falling into the basal receiving hopper. The material passing through the Entoleter thus encounters two major impactions and this is responsible for the control of all free living insect stages.

Working with moving grain, Loschiavo (1978) found that dropping of adult insects into free-flowing grain caused substantial mortality, while Bahr (1991) found that with a range of stored grain insects, passing through a pneumatic conveyer caused between 48 and 95% mortality of adult beetles, while four passes through a vacuum cleaning system caused between 72 and 100% kill, depending on the species, of all developmental stages. Moving grain by screw auger has also been shown to reduce the number of free living stored product insects and mites (White *et al.*, 1997).

Free-living insects prove easier to control than those developing inside the grain. While subsection of grain to impaction machinery cannot eliminate internal grain feeders below levels causing damage to the grain (Stratil *et al.*, 1987), the technique offers a substantial contribution to IPM programmes (Beckett, 2010).

In studies on bruchid infestation of beans, Quentin *et al.* (1991) found that gentle tumbling of beans every 8h over a 2 week period reduced population growth by 97%. The effect was explained by prevention of first instar larvae from entering the seed after egg hatch. The use of disturbance and impaction techniques merit further investigation and development in the field of insect control.

### 15.3.7 Inert dusts

Inert dusts may be: clays, sands, ashes or earths; diatomaceous earths (fossilised remains of diatoms consisting mainly of silica with small amounts of other minerals); silica aerogels (very light, non-hygroscopic powders that are effective at lower dosages than diatomaceous earth formulations); and



non-silica dusts, such as phosphate and lime. Inert dusts have a long history of use for protection of crops such grain or legumes (Ebeling, 1971; Golob and Webley, 1980; Quarles, 1992; Giga and Chinwada, 1994). Inert dusts are rapid in their lethal action under favourable conditions for most pests but *Trogoderma* species do not appear to be effectively controlled. Available data on responses of immature stages of pests that bore into grain is limited, although population growth is suppressed, and recent tests have demonstrated the efficacy of diatomaceous earth (DE) dusts against mites (Cook and Armitage, 1999; Collins, 2006).

Several inert dusts are registered in some countries for treatment of grain and pulses against insect pests. They are particularly useful in dry conditions to control pests in grain and storage structures (Fam *et al.*, 1974; Fields, 2006). They can form a useful part of IPM strategies as sprays applied to the fabric of the building to minimise residual infestation and migration of pests. Inert dusts have also long been used as carriers for insecticides, but current initiatives seek to improve formulations for use alone. Modern formulations based on DE are designed to minimise their abrasive properties (to protect conveying machinery) and enhance their insecticidal action as desiccants by promoting their capacity to selectively absorb insect cuticular waxes. They provide a direct alternative to chemical protectants for effective pest control in dry grain (Desmarchelier and Dines, 1987; Collins, 2006), but lose effectiveness at humidities above about 75% RH or above 14% grain moisture content (Le Patourel, 1986; Fields, 2006). Dryacide, an activated DE, is in widespread use in Australia in the grain handling industry, and Protect-It™, an enhanced DE formulation is widely used in North America. Some formulations are accepted as suitable for use on foods certified as 'organic' in some countries. DEs are widely used as food and processing additives.

Inert dusts do not require capital equipment, are relatively non-toxic, provide continued protection, and do not affect baking quality (Desmarchelier and Dines, 1987; Aldryhim, 1990). Their disadvantages are decreased flowability of grain, visible residues that can affect grading, and decreased bulk density of grain. Marine silicates may give rise to dust problems in the workplace, with some risk of carcinogenicity, a problem not encountered with DEs of fresh water origin. Korunic *et al.* (1996) summarise the uses and properties of DE formulations that overcome many of the problems associated with this technology.

### 15.3.8 Irradiation

The process of irradiation involves the use of gamma energy, accelerated electrons or X-rays to penetrate the commodity. The most common radiation source is cobalt-60, which provides a constant field of ionising energy. The effectiveness of treatment for insect control and effect on food quality is related to the energy delivered. While operating costs are low, the capital

investment for irradiation facilities is high, and the infrastructure must be present to support a commercial radiation facility.

Disinfestation by irradiation has been under investigation since 1912. More recently Brower and Tilton (1985) and Tilton and Brower (1987) summarised the radio-sensitivity data on 40 stored-product pest species to identify options for quarantine uses and disinfestation of grain and grain products. These data showed that pests vary in their sensitivity to radiation. Generally, the developmental stages are more sensitive than adults, females are more sensitive than males, and adults are more easily sterilised than killed. Comparing groups, beetles and mites are more sensitive than moths, and fruit flies are more sensitive than beetles. The use of irradiation for quarantine is hampered by the fact that the insects are usually damaged and incapable of completing development or sterilised and incapable of reproduction, but may remain alive in the commodity for weeks afterwards.

Selection of the type of irradiation equipment to be used depends on whether the commodity is to be irradiated in packages or in bulk, the quantity of product to be treated and other factors. Accelerated electrons are less effective than gamma rays for insect control, lacking the penetrative power of the latter (Adem *et al.*, 1978). However they are inherently easier to work with as they can be switched on and off. Gamma irradiators can treat packaged or bulk products; and accelerators can more effectively treat bulk products in thin layers (2–5 cm thickness). Irradiation is effective at all temperatures with either bulk or bagged commodities. The dosage of irradiation which can be used is limited by effects on the quality of the commodity. Irradiation at some doses may stop germination of grains and seeds; for instance it is not suitable for use on malting barley. Like fumigation, irradiation does not confer residual protection against pests, so packaging materials or post-treatment storage controls should be employed to prevent reinfestation.

In Indonesia, about 300 tonnes of bagged rice per week have been irradiated as part of government rice storage practice since 1994. It is an effective treatment against *Sitophilus oryzae* (rice weevil) at a minimum dose of 0.40 kGy. The packaging materials are polyethylene liners plus polypropylene outer bags sewn shut with polyester thread. A full-scale commercial electron beam accelerator was formerly in use at Odessa, Ukraine, for the treatment of imported grain (Zakladnoi *et al.*, 1982), but is no longer operating.

Concerns hampering public acceptance of irradiated foods appear to be diminishing, especially in the light of increased public awareness of irradiation as a means of combating microbial contamination, but there is still some opposition. However, there are few agreements enabling the movement of irradiated products in international trade. It is approved for at least one food use by 41 countries although the treatment is primarily for disinfestation purposes in just over half of these (Anon., 1998).

### **15.3.9 Screening, sorting and sanitation**

The screening and sorting of many harvested crops is an effective method of preventing infested produce from entering the food chain in developed countries and in classifying produce according to suitability for animal or human feed in developing countries. For example Compton and Sherington (1999) describe a simple technique for classifying maize cobs into categories based on the level of damage by visual comparison with standard pictures, which is suitable for use by subsistence farmers. Screening and sorting measures are designed to remove pests or prevent their access to the product or commodity. Systems have been designed to separate out infested grains by projection through air or by aspiration technology. In flour mills screens and sifters remove insect stages and fragments from the production line.

Good sanitation practice is a vital component in the control of food pests, regardless of any other practices carried out. It reduces pest food and harbourages within and without a structure by regularly removing waste and debris during vacuum cleaning, sweeping and washing. Construction and maintenance also play major roles in reducing pest harbourages and denying pest access to structures. New machinery and facility construction should include pest preventative design as a priority. For existing facilities, problems may only be solved by changes to the structure such as repairs and closures of pest entrances and niches, caulking wall joins, removing ledges and catchments and applying new surface coverings, but costs can prove prohibitive.

Other aspects of good warehousing practice, e.g. stock rotation and, where applicable, insect-proof packaging, also reduce pest population pressure. The retention of polythene sheeting on a stack after a fumigation is an effective means of preventing reinfestation, as demonstrated in trials and current practice in South East Asia (Annis, and Graver, 1990). Other measures include sieving, screening, separation by projection and aspiration. Whereas none of these methods is capable alone of achieving sufficient control, they can be useful in combination with other measures. The topic of physical removal and exclusion was reviewed with other physical control methods by Banks and Fields (1995).

### **15.3.10 UV light traps**

UV light traps are widely employed to monitor and control flies in bakeries, restaurants and food processing plants, often being placed to help draw insects away from entrances and out of buildings. The traps also attract and kill flying moths but they are not very effective in reducing storage moth populations. Many types of fly are hygiene threats in industry, including house flies, blow flies, fruit flies and drain flies, each originating from different sources of hygiene failure. They can transmit many faecal and

oral-borne pathogens. UV traps can help to reduce fly problems when adequate attention is also paid to remove potential breeding sites.

## 15.4 Chemical control of pests

For most of the 20th century chemical control was mainstay of the agricultural and food industries but of late there has been increasing pressure to minimise chemical use and reliance on pesticides in the interests of avoiding long-term health and environmental consequences. Chemicals still play a vital role in the protection of food commodities and products but the compounds remaining available for use are declining in number and more attention is being paid to non-chemical alternative control measures.

### 15.4.1 Attractants and repellents

Many compounds exhibit properties which either attract or repel insects. The chemical control of cockroaches, augmenting high standards of hygiene, now relies heavily on the performance of baits which are laid down to attract the insects to take up a lethal or sterilising dose. Most insecticides are repellent and the formulation of baits to overcome this can be difficult. The newer generation of gel formulations has met with greater success in the control of cockroach pests (Appel, 1990; Durier and Rivault, 1999), replacing insecticidal sprays as a control strategy.

For other food pests utilisation has been made of chemicals produced by the pests themselves to act as cues for mating or food location. These chemicals, produced by one member of a species and transmitted externally to another member of the same or a related species, influence the behaviour or physiology of individuals picking up the stimulus. Such compounds are known as semiochemicals, of which the most studied group are the sex pheromones. In most cases the female releases a chemical into the air that both attracts and sexually stimulates males of the same species. The sex pheromones of several storage pests, both Coleoptera and Lepidoptera, are among the earliest identified pheromone molecules. The primary sex pheromone component of the phycitine moths, *Z,E*-9,12-tetradecadienylacetate (ZETA) (Kuwahara *et al.*, 1971), is highly susceptible to degradation when exposed to light or air, a factor taken into account when formulating baits. Formulations of this chemical have been used for some time to monitor and disrupt mating of Indian meal moth in warehouses (Pierce, 1994). Aggregation pheromones are another group of stimulants attracting mobile stages of both sexes to a food source. Pheromones of this type have been identified for many stored product beetles of the families Bostrichidae, Cucujidae, Curculionidae, Nitidulidae, Sylvanidae and Tenebrionidae and

also for some pyralid and tineid moths. The use of pheromones in the food industry has been reviewed by Phillips (1997) and Cox (2004).

Pheromones can be used as lures in traps to monitor storage pest populations or they may be employed as part of a control system via mass trapping coupled with an insecticide or pathogen dissemination source, or as a means of mating disruption (Burkholder, 1985). Mass-trapping has been used with success to control Mediterranean flour moth in flour mills (Trematerra and Gentile, 2010). However, while populations can be suppressed, techniques based on attractants rarely achieve total disinfection.

#### **15.4.2 Botanicals and natural products**

These compounds are derived from plants, and include plant alkaloids, secondary metabolites and essential oils. At present, the only botanical-based insecticides in widespread use in developed countries for protection of stored food products are pyrethrins extracted from pyrethrum flowers and more recently azadirachtin extracted from neem. The application of many botanicals is limited in developed countries because often considerable quantities need to be applied to the raw food material and there are concerns about transferring odours or off-flavours to milled or processed products. A wide variety of plant materials are still used by subsistence farmers for harvest protection in developing countries. Many of these are under active investigation, essential oils in particular attracting much research effort, often in conjunction with other control agents (Rajendran and Sriranjini, 2008; Isikber, 2010; Perez *et al.*, 2010; Mikhael, 2011; Ben Jemaa *et al.*, 2012). As natural products are not readily patented, a company sponsoring the necessary toxicological testing to gain registrations for use is at risk from competitors. This has been a stumbling block for their successful introduction as pest control agents except when data for a product is already available because of previous initiatives to gain approvals for use as a food additive.

#### **15.4.3 Fumigation**

Fumigation is an important control measure in the food industry for the treatment of incoming raw materials, either before leaving the country of origin or on arrival at the dockside before distribution. It is the primary control procedure applied on discovery of infestation in bulk commodities in store or during transport, and for whole site treatment of food processing premises. For effective application, fumigation relies on achieving an effective seal on the bulk commodity or building to be treated. Plastic enclosures are in use for bagged products, either as ready available kits with zip seals (Newton, 1991; Navarro *et al.*, 1997) or as tents constructed glued and sealed on site (Nataredja and Hodges, 1990; Annis and van Graver, 1990). Polyethylene is often used as fumigation sheeting but better gas

retention is obtained with nylon or polyvinyl chloride (PVC) materials or laminates (Chakrabarti *et al.*, 1995). The number of fumigants in widespread use has been falling steadily in recent years, originally because of concerns over toxicology and the formation of toxic residues, and more recently over concerns with ozone depletion, ecosystem damage and safety of application.

Carbon bisulphide was one of the first modern era fumigants to be introduced, back in the 1870s (Cotton, 1956). Once widely used as a fumigant for bulk and bagged grain, and applied as a 'liquid fumigant' in a mixture with carbon tetrachloride or alone, in most countries its use has been discontinued and registration has lapsed. Application to large bulk storage is restricted by the potential fire hazard of the material. There is still some use in China and Australia where it is applied to small lots of grain (c. 50 tonnes) in farm storage.

Carbonyl sulphide is a new fumigant closely related to carbon bisulphide and registered for use on grain in Australia (Banks *et al.*, 1993a). The gas is highly penetrative and sorption on to wheat is very low. Stored cereals contain low natural levels of the gas and mammalian toxicity is low. The fumigant has been shown to be highly effective against stored product pests (Zettler *et al.*, 1997; Weller and Morton, 2001).

Ethyl formate has a long history as a fumigant for grain and dried fruit, and with the loss of methyl bromide has been the subject of renewed interest as Vapormate, a cylinder-based formulation of one part ethyl formate to five parts of carbon dioxide. It is registered for use on grain, fresh produce and packaged food in Australia (Ryan *et al.*, 2006) and for use on dates in Israel (Finkelman *et al.*, 2010). The action of ethyl formate against pests is quite rapid with control being achievable after exposures of only a few hours (Hilton and Banks, 1997). However, the gas is highly sorbed by commodities, especially at raised humidity, and it can be difficult to attain adequate distribution even with the assistance of carbon dioxide, so longer exposures are needed to be effective in practice. Ethyl formate can also be corrosive to unpainted metals at high humidity.

Ethylene oxide has been used extensively to reduce microbial contamination in food commodities such as spices and some processed foods and coincidentally provides insect control. It was formerly widely used for insect control on grain (Cartox system) and dates. Because of its flammability, ethylene oxide was generally supplied in mixtures with inert diluents such as CO<sub>2</sub> or HCFCs. Ethylene oxide reacts with chemical constituents of some food commodities producing potentially carcinogenic compounds, such as ethylene chlorohydrin (Wesley *et al.*, 1965), but with carefully controlled application in chambers it is one of several compounds under consideration as a niche alternative for some methyl bromide quarantine uses. Its current use, as a 9% mixture in CO<sub>2</sub>, is restricted in most countries to sterilisation of medical devices and instruments in vacuum chambers and quarantine treatments of non-food products (Ryan *et al.*, 2010).

Hydrogen cyanide was previously used widely as a fumigant for durable commodities, mills, factories and transport, including aircraft. It is highly toxic and rapidly lethal to insects but readily sorbed by commodities particularly under humid conditions, which can lead to hazards because of delayed ventilation of gas. It was superseded by methyl bromide and phosphine, both of which are less hazardous for use by trained operators, better able to distribute through bulk commodities, less expensive, and, in many cases, more effective. Cylinders of liquid HCN are unstable and cannot be stored for long periods. However, HCN can readily be generated *in situ* from sodium cyanide formulations (Anon., 1989). Today its registration has lapsed in most countries.

Methyl bromide was the fumigant of choice for foodstuffs and stored products for more than 50 years. It has a very wide spectrum of toxic action and was also widely used as a soil sterilising pre-plant fumigant. As a result of its high toxicity and rapid action against insects, its superior powers of penetration and greater ease of handling, it largely replaced the fumigants hydrogen cyanide and ethylene oxide. Since 2005, however, the compound has been phased out except for quarantine and pre-shipment uses in developed countries under the Montreal Protocol, an international agreement on the elimination of ozone depleting chemicals run by the United Nations Environment Programme (UNEP, 2006). Developing countries are scheduled to follow suit in 2015.

For fumigations under gas-proof sheets in warehouses, methyl bromide is usually effective within 24 hours. It can also be used under vacuum in chambers, reducing treatment times to 3 or 4 hours. The rapid speed of action made methyl bromide fumigation a particularly convenient treatment where the commodity could not be held for long periods for logistical reasons, such as at ports during import and export. This speed of action is also very important in quarantine treatments to disinfest perishable commodities such as fresh fruit and cut flowers. In practice, the down-time for fumigation includes the actual exposure period to the fumigant, the preparation time of the enclosure beforehand and the time at the end of the exposure, when residual gas is aired off from the treated commodity. For a flour mill, even with a fast-acting fumigant like methyl bromide, this can represent two and a half working days.

Phosphine is extensively in use as a fumigant for treating cereals and legumes, and since the withdrawal of methyl bromide is the most commonly used fumigant. It ranks as one of the most toxic fumigants known, and is used at low concentrations. Acting via the oxidative cycle for energy production, effects on pests tend to be accumulative and long exposures are required, particularly at low temperatures, for kill of all stages. Phosphine penetrates well into commodities and can be removed rapidly by aeration after treatment. The gas will react with copper, silver and gold and can cause corrosion of electrical equipment under humid conditions (Bond *et al.*, 1984; Brigham, 1998). Formulations releasing phosphine gas are available



worldwide. Most are tablets or pellets containing aluminium phosphide formulated with ammonium carbamate or urea to lessen the risk of spontaneous flammability which can occur if the gas concentration exceeds 1.8% by volume in air at normal atmospheric pressure. There are also formulations in plate rather than tablet form based on magnesium phosphide. There are many publications describing application of phosphine to stored grain and other durable commodities (e.g. Bond, 1984; Banks, 1986; Noyes *et al.*, 1997). Typically, metal phosphide formulations are added to the grain, or placed on the grain surface or near the product to be fumigated within the fumigation enclosure. Phosphine is generated *in situ* by the reaction of atmospheric moisture with the metallic phosphide (Bond, 1984). Phosphine is also available commercially from generators, in pressurised gas cylinders as a non-flammable 2% mixture in liquid carbon dioxide and as a 1.7% mixture in compressed nitrogen.

The use of phosphine should follow these guidelines:

- The commodity temperature should be more than 15 °C although certain pests are susceptible down to 5 °C with long exposures.
- Exposure periods need to be prolonged for kill of all developmental stages of pests, 3 weeks being required at 15 °C (for the most tolerant pests) reducing to 4 days at 30 °C.
- For aluminium phosphide formulations, the equilibrium relative humidity within the commodity should be more than 30% to ensure full evolution of phosphine from the formulation within the exposure period.
- Well-controlled techniques must be used to avoid the rapid decline of concentration levels in the enclosure and inadequate exposure times, which are known to lead to the development of pest resistance.

As some stages in the life cycle have reduced sensitivity to the gas and carry on developing under gas, the period of exposure has a much more important role than concentration levels in increasing the efficacy of phosphine. Eggs and pupae are often very much more tolerant than larvae and adults. Mites are difficult to control with phosphine since the egg stage is highly tolerant and unlike insect eggs, development appears to be delayed under gas.

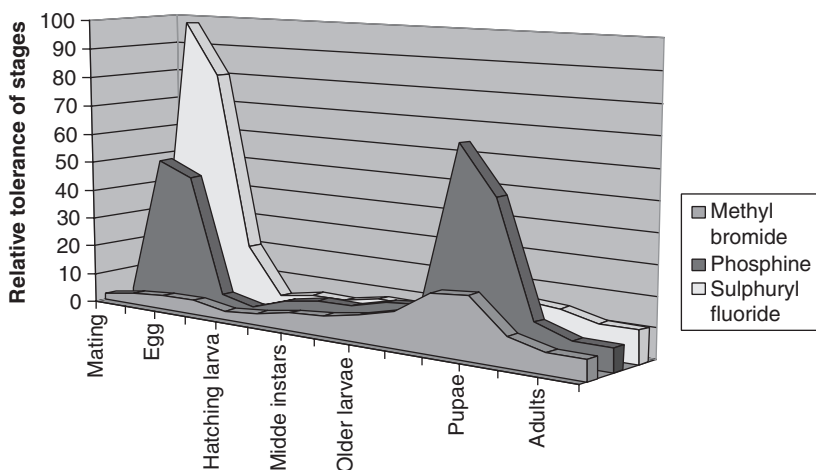
Phosphine is widely used for treating infestation in bulk and bagged grain and grain products in many countries. Shipboard in-transit fumigation with phosphine is now a well developed technology (Leesch *et al.*, 1986). It requires ships of appropriate design and stringent safety precautions (IMO, 1996). Phosphine is also used for treatment of dried fruit, nuts (except walnuts which can pick up a taint and change colour), beverages and most spices. Most pests of dried fruit and nuts are highly susceptible to phosphine and shorter exposure times can be used than with stored grain. In the latter case, the longest periods are needed for the control of *Sitophilus* spp. (Hole *et al.*, 1976). These do not attack dried fruit, nuts, cocoa, coffee or spices.



Recent developments in phosphine fumigation technology, including the arrival of improved phosphine generating systems (e.g. Horn and Horn, 2006), have increased the competitiveness and effectiveness of phosphine use in comparison with other treatment methods. Discussion of recent advances in phosphine treatment of grain against infestation can be found particularly in Lorini *et al.* (2006) and Carvalho *et al.* (2010).

Sulphuryl fluoride was developed in the late 1950s as a structural fumigant, mainly for termite control. The efficacy of this product is well researched and understood. It provides good penetration, requires a short fumigation period of approximately 24 h, and airs off within 6–8 h. In many countries sulphuryl fluoride has been registered for use in empty food processing facilities and on certain commodities to replace methyl bromide. It is toxic to post-embryonic stages of insects but the eggs of many stored product species are very tolerant, especially at lower temperatures, requiring concentrations of over 50 g/m<sup>3</sup> and exposures of up to 3 days for complete kill (Kenaga, 1957; Bell and Savvidou, 1999; Bell, 2006). In this respect it resembles phosphine rather than methyl bromide (Fig. 15.1).

Some other compounds have been considered for use as fumigants. Cyanogen (ethanedinitrile) is under consideration as an alternative grain fumigant and sterilant in Australia. It has been patented for this use. Methyl iodide has similar properties to methyl bromide, its activity towards stored product pests has long been reported in the literature (Muthu and Srinath, 1974; Kostjukovsky *et al.*, 1997) and recently it has been registered in the USA as a soil fumigant (UNEP, 2011). Methyl isothiocyanate, introduced in 1959 by Schering AG as nematicide under the trade name Trapex, has been found effective against grain weevils (all stages) at a very low dosages



**Fig. 15.1** Exposure time and efficacy: variations in tolerance towards three fumigants as insect development proceeds from egg to adult.

(Ducom, 1994). However, this compound has to be very well mixed with the grain because it is highly sorbed and it could be more useful as a fumigant for perishable commodities (Ducom and Vinghes, 1997). Methyl phosphine has a specific action against phosphine resistant strains, being more toxic to these than to susceptible strains, but has a short half life on commodities (Chaudhry *et al.*, 1997). Ozone has a sterilising action against bacteria and viruses, but breaks down rapidly. Activity has been found against many stored product pests, but for kill within a few hours very high concentrations are needed (McDonough *et al.*, 2011), which is difficult to achieve in practice. Alternatively continuous generation and distribution of the gas is needed to maintain concentrations above 50 ppm for more prolonged exposure (de Sousa *et al.*, 2006). Propylene oxide is in use as a disinfection agent for raisins in the US and has been subjected to renewed investigation as an insecticidal fumigant for nuts (Isikber *et al.*, 2006).

#### 15.4.4 Insect growth regulators

The term insect growth regulator (IGR) is used to describe compounds which interfere with the life cycle of pests by action on the hormonal control of development, either as agonists or as antagonists of juvenile hormone (JH). IGRs also include chitin synthesis inhibitors which affect development by halting moulting. Most IGRs have low toxicity to vertebrates and are more pest-specific than conventional contact insecticides. This gives them the advantage of being able to be used in combination with predators and parasitoids (Oberlander *et al.*, 1997). They are, however, generally used in a similar way to contact insecticides and are subject to similar requirements for registration. Offering long-term protection to treated commodities, their long persistence on foodstuffs limits their use where the detectable presence of residues is a problem. They are also relatively costly and normally do not achieve control quickly, adult and larval pests being able to feed and damage products for some time after treatment.

IGRs such as methoprene and hydroprene act against insects via ingestion or contact, while others like the chitin synthesis inhibitor diflubenzuron act only via ingestion. Methoprene and hydroprene have been registered for use in the protection of a variety of stored commodities in a number of countries, including the USA, Australia and the UK and are effective against many stored product pests either alone or in combination with other control agents (Mohandass *et al.*, 2008; Jensen *et al.*, 2010; Wijayaratne and Fields, 2010).

Monconduit and Mauchamp (1998) found that very low level (ppb) treatments of the eggs or larvae of moths just after hatching with fenoxycarb, another JH agonist, caused lethal disruption of moulting throughout the larval period, and virtually none of the insects survived to the pupal stage. Like other insecticides there is always the potential for resistance to IGRs

to become a problem and further studies are needed for development of effective protocols for their use in commodity protection.

#### 15.4.5 Smokes and mists

Smokes (solid particles dispersed in air) and mists (liquid droplets dispersed in air) have in the past been popular for use in food processing facilities for the control of flying insects. Their popular linkage with fumigation is misleading as they have no penetrative powers into commodities or voids in structures and are ineffective against insect stages hidden from view. The reliance on smoke bombs and mist dispensers thus does not deal with the root problem of infestation and is best regarded only as an adjunct to other control procedures.

#### 15.4.6 Synthetic contact insecticides

Synthetic insecticides include analogues of pyrethrum (pyrethroids), organochlorine (now largely out of use because of persistence in the environment and residue problems) and organophosphorus compounds (OPs). Most are unsuitable for use on processed foods. Although the organochlorine lindane ( $\gamma$ -hexachlorohexane) has long been discontinued as a grain protectant in developed countries, residues are still occasionally encountered in grain, indicating continued use of stocks elsewhere in the world. OPs still form an important group of grain protectants in current use. The stability of deposits on harvested grain varies widely with the active ingredient, the particular formulation and the prevailing ambient conditions. Maximum application rates for raw cereal grains and permitted residue levels have been laid down by the Codex Alimentarius Commission (1992). The rate of degradation increases both with temperature and water activity (moisture content), while toxicity to insects also increases with temperature. In consequence, persistence of the biological effectiveness will depend upon the compound used. For example, typically dichlorvos acts quickly and degrades within a few days, while malathion takes several weeks, and pirimiphos-methyl many months to degrade. Most OPs have limited efficacy against the bostrichid beetles *Rhyzopertha dominica* and *Prostephanus truncatus*.

Dichlorvos is unique amongst grain protectants in its rapid action against pests and ability to subsequently vaporise off from grain, but registration has lapsed in many countries. In the absence of resistance, and where still approved, it can be sprayed on to bulk grain within a few days of export to disinfest a cargo. In other circumstances, such as the storage of grain from one harvest to the next, there are advantages in applying a compound that breaks down slowly enough to give protection against infestation throughout the storage season. As a whole, grain protectants do not readily penetrate bagged or bulk grain. This restricts their utilisation substantially as normally

they must be applied to the grain during handling, e.g. prior to bagging or during conveying. The use of grain protectants varies widely with country, market preference and local regulations. Where permitted, and where pest resistance is not a problem, they provide a useful means of preventing infestation. They are also used as sprays on storage structures and the surfaces of bagged or bulk grain as part of a pest management programme. Besides dichlorvos, pirimiphos-methyl, chlorpyrifos-methyl, fenitrothion, etrimphos, methacrifos and malathion have all been used in the protection of stored grain or food storage facilities, but registrations are becoming fewer as more stringent demands for continued clearance are being made by registration authorities. Currently there are concerns regarding possible toxic effects of low residue levels in food products and further actions against the use of organophosphates on food commodities are likely in the future.

Synthetic pyrethroids (e.g. deltamethrin, bioresmethrin, permethrin, cyfluthrin) are quite stable on grain and in some circumstances their insecticidal activities may persist up to 2 years (Snelson, 1987). Their action is much less sensitive to temperature than organophosphorus insecticides. In contrast to OPs, pyrethroids are active against bostrichid beetles at a much lower dosage than for most other storage insect pests. A disadvantage of these pesticides is their relatively high cost. In many situations pyrethroids are added in combination with a synergist, piperonyl butoxide, to increase effectiveness and reduce cost, and are often used in conjunction with other control agents (Jensen *et al.*, 2010).

Recently another group of insecticides has appeared on the market, based on metabolites from the actinomycete bacterium *Saccaropolyspora spinosa* Mertz and Yao which occurs in soil. The active ingredient is registered for use on a very wide range of crops in the US including stored cereals (Bonjour *et al.*, 2006). The formulation spinosad has proved to be effective against beetles resistant to other contact insecticides and also psocids (Nayak *et al.*, 2005). Tests on new formulations are in progress (Hertlein *et al.*, 2011).

## 15.5 Biological control of pests

Biological agents which range from microbiological pathogens to predatory insects are generally host specific and are best considered as preventive control measures, avoiding the build-up of pest populations. Arthropod parasitoids and predators may occur naturally in stored commodities, but rarely suppress storage pest populations before unacceptable damage occurs. Therefore, mass-release or augmentative approaches are needed to overwhelm pests before they can do harm. Pathogens of insects include bacteria, viruses, protozoa, nematodes and fungi. This wide spectrum of organisms occurs naturally though not necessarily in the stored food

environment. They therefore have to be applied to the specific situation where the choice has been made for their use as control agents.

### 15.5.1 Bacterial pathogens

The toxin-producing bacterium *Bacillus thuringiensis* (Berliner) (Bt) is the principal pathogen in use for control of lepidopterous pests and some others in agriculture. It requires a high pH, found in the gut of Lepidoptera and some beetle species, for optimal replication. In the stored product field, commercial formulations provide a control method for almond moth and Indian meal moth when applied to grain or other durable commodities as an aqueous suspension or as a dust. These are effective when all the grain is treated, or when just several inches of the surface layer are treated, because lepidopterous larvae usually live near the surface of the bulk. Residual activity against susceptible insects can last for more than a year but the problem of resistance to Bt, has arisen in some moth populations (McGaughey and Beeman, 1988). Bt is approved in the USA and many other countries for use as a stored product protectant. Vail *et al.* (1991) report the screening of several lines of transgenic walnut with high levels of the Bt insecticidal crystal protein fragment that arrest development or kill larvae of codling moth, navel orangeworm, and Indian meal moth, the principal pests of stored walnuts in California. Recent studies on the biosurfactant produced by another bacillus, *B. subtilis* (Ehrenberg), have revealed potency against *Ephestia kuehniella* larvae that is stable under a variety of environmental conditions including a pH range of 5 to 9, thus offering some advantage over the more potent toxins from Bt (Ghribi *et al.*, 2012).

### 15.5.2 Fungal pathogens

Entomopathogenic fungi have long been known to have potential for combating insect pests but there have been concerns over their specificity of action and safety. One species, *Beauveria bassiana* (Balsamo) Vuillemin, has recently been revisited as an active research topic for use against pests of cereals (Hildago *et al.*, 1998; Taylor *et al.*, 2011). Another genus of fungal pathogens with potential for stored product pest control is *Metarhizium*.

### 15.5.3 Parasites and parasitoids

Many species of ichneumonoid, bethylid or chalcidoid wasps utilise stored product insects as hosts. The primary target pest species are moth larvae or eggs and various beetle larvae. Some of the more effective parasitoids are the ichneumonoid braconid *Bracon hebetor* = *Habrobracon hebetor* (Say), which attacks moth larvae (Cline and Press, 1990) and the chalcidoid

trichogrammatids *Trichogramma evanescens* Westwood and *T. pretiosum* Riley which attack eggs (Brower, 1988). The ectoparasitic bethylids *Cephalonia gallicola* Ashmead and *C. tarsalis* Ashmead attack the larvae of a range of beetle species.

*Bracon hebetor* has commercial use in South Africa for reducing the need for fumigation of stacks of bagged grain (Anon., 1991) and is used to control Indian meal moth in stored peanuts in the south-eastern USA. The ichneumonid *Venturia canescens* (Gravenhorst) has also been used for the control of *Ephestia* moths (Press, 1989). Baker and Throne (1995) utilised an insecticide-resistant strain of the chalcidoid pteromalid *Anisopteromalus calandrae* (Howard) for control of malathion-resistant rice weevils on malathion-treated wheat. Flinn *et al.* (1996) report effective control of the lesser grain borer in large-scale bulk wheat at moderately high temperatures with the pteromalid parasitoid *Choetospila elegans* (Westwood). The principal drawback for the use of parasitoids in pest control is that often the presence of any insects or insect fragments in the food production chain is unacceptable, confining most deployments to the raw commodity storage stage.

#### 15.5.4 Protozoan pathogens

Sporozoan parasites are common and widespread among stored product insects, causing debilitating illnesses and reducing population growth (Arbogast, 1984). Larvae and adults of *Cryptolestes* spp., *Tribolium* spp. and the moth *Sitotroga cerealella* may harbour pathogenic schizogregarines such as *Farinocystis tribolii* Weiser and *Mattesia dispora* Naville in their hind gut. The microsporidian *Nosemia whitei* Weiser is a common pathogen of *Tribolium* spp. and other beetle species while *N. plodiae* Kellen and Lindegren infects phycitine moths. The potential of these organisms as control agents merits further research and development.

#### 15.5.5 Predators

The effectiveness of the predatory warehouse pirate bug, *Xylocoris flavipes* (Reuter), in regulating stored product beetle and moth populations has been evaluated in simulated storage premises (Press *et al.*, 1975; Brower and Mullen, 1990), the introduction of large numbers of pirate bugs suppressing pest populations quite rapidly. The histeoid beetle *Teretrius* (*Teretriosoma*) *nigrescens* (Lewis), a natural predator in Central America, has been used successfully to suppress populations of the serious maize pest *Prostephanus truncatus* in Africa (Giles *et al.*, 1996).

Predatory mites are another group of predators, preying on insect eggs and small larvae. The pyemotid mites *Pyemotes ventricosus* (Newport), *P. tritici* L.-Fossat and Montagne, *Acarophenax dermestidarum* Rack and *A. tribolii* Newstead and Duvall prey mostly on insects while the ascid mite

*Blattisocius dentriticus* (Berlese) and the cheylitid *Cheyletus eruditus* (Schrank) prey on stored food mite species.

### 15.5.6 Viruses

Entomopathogenic viruses (primarily baculoviruses) have been widely studied for the control of storage moth pests (Hunter and Dixel, 1970; Kellen and Hoffmann, 1987), but have not been isolated from storage beetles. Crystalline occlusion bodies containing the virus are the natural choice for insecticidal action. Virus particles attack the larval gut but surviving adult females may pass on the infection to eggs laid. The granulosis virus (PGV) of *Plodia interpunctella* and the nuclear polyhedrosis virus (CGV) of *Ephestia cautella* have been tested as a part of integrated control programs in the USA (Vail *et al.*, 1993).

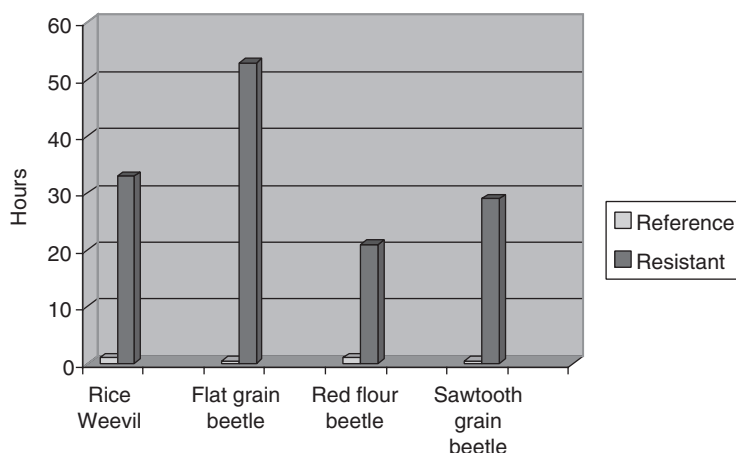
## 15.6 Threats to successful control

### 15.6.1 Pest resistance

Any chemical with a specific mode of action is vulnerable to the development of resistance in pest species. Resistance is known to all the major classes of chemical control agents and to many physical and biological control methods also. The natural spectrum of tolerance to a toxicant is an excellent indicator of the potential for resistance to develop among pest species. Hence, the fumigant methyl bromide has a comparatively narrow tolerance spectrum among insects and few instances of resistance have been reported after over 50 years of use, while the fumigant phosphine has a very wide tolerance spectrum evident even among the developmental stages of the same species, and pest resistance has become a real problem, particularly among beetle and psocid pests.

All the organophosphorus insecticides have generated resistance of sufficient magnitude to cause control failures and there is often strong cross-resistance between compounds. For control of the lesser grain borer in Australia, for instance, the use of organophosphorus compounds is no longer an option (Collins, 1994). High levels of resistance to the fumigant phosphine have been measured in the laboratory in several species of stored-product beetle pests originating from parts of Africa and the Indian subcontinent, following frequent use of the fumigant in conditions of poor gas retention (Taylor, 1989). In the past decade control failures attributable to increasing levels of phosphine resistance have been reported from all over the world (Lorini *et al.*, 2007; Nayak *et al.*, 2010). Insect populations are capable of developing resistance to phosphine relatively easily where there is malpractice or in situations where complete control of pests is difficult to achieve in a large structure such as a mill. Short fumigation periods (e.g. less than 3 days) employing low concentrations of phosphine





**Fig. 15.2** Time for 50% knockdown of beetle strains exposed to phosphine.

at high ambient temperatures, provide the ideal conditions in which insect resistance can develop.

Phosphine resistance can now be detected rapidly by observing the rate of knock-down of adult beetles in desiccators at  $0.35\text{--}0.4\text{ mg L}^{-1}$  (Savvidou *et al.*, 1994) or at 3000 ppm ( $4.5\text{ mg L}^{-1}$ ) (Steuerwald *et al.*, 2006). Whereas susceptible beetles are all knocked down within a few minutes, or at the lower dose a couple of hours, resistant insects remain active (Fig. 15.2).

Resistance management is an important consideration when using phosphine. The considerable volume of work on phosphine resistance and mode of action is reviewed by Chaudhry (1997). The effect of resistance to phosphine can at present be overcome provided that the required gas concentration can be maintained for the longer exposure periods needed for kill of the more tolerant strains (Nayak *et al.*, 2010). In leaky situations such as in unsealed silos or sheds containing floor-stored grain, insect control may be carried out by a continuous input of fumigant atmosphere by injecting a phosphine–carbon dioxide or nitrogen mixture from a generator or pressurised cylinders into an airflow system. However, for dosing with conventional metal phosphide formulations, the degree of gas-tightness of the enclosure should be improved as far as possible so that gas may be retained for a sufficient period. A closed loop circulation system can be installed to keep an even gas concentration level throughout the structure (Noyes *et al.*, 1997). In spite of such efforts, multiple dosing may still be necessary with such formulations for efficacy against resistant strains.

Resistance has become a major consideration in the continued use of many contact insecticides and fumigants such as phosphine. With only a restricted number of compounds available for use resistance is a serious



threat. Solutions such as alternating or rotating the use of toxicants have been proposed but are difficult to administer. Better prospects ensue from measures aimed at reducing selection for resistance, such as use of physical or biological alternatives, or by pursuing research to develop new compounds which have activity against resistant strains.

### **15.6.2 Registration and compound availability**

Although the availability of pest control agents to treat commodities is much relied upon in every country, the post-harvest and stored product market in any one country or state does not offer the prospect of cost recovery to multinational chemical manufacturers trying to develop and register new products. Each country has its own registration procedures and decides upon the acceptable daily intake (ADI) level for each compound and defines the maximum residue level (MRL) to be allowed in treated products. In addition there are many other data requirements that have to be supplied by potential registrants. The cost of registration of a new active ingredient can thus prove prohibitive for a particular market. The stored product and food sector is highly complex, being very much sub-divided on a commodity basis, requirements differing between commodities and products. Though the problem for registration of new active ingredients, and even for new formulations of an existing active ingredient, has been highlighted, governments have generally not provided any realistic support for such minor use areas. As a result the number of chemicals remaining available for stored food protection is very small, and as registrations lapse or are withdrawn, few replacements are entering the pipeline. Moves to harmonise registration procedures as currently being explored within the European Union are needed to ease the situation and prevent gaps appearing in the pest control armoury for a wide range of products.

## **15.7 Conclusion**

The control of stored product and quarantine arthropod pests remains an active field of research and practice. The pursuance of measures ensuring good sanitation is of paramount importance. Storage of crops and commodities most often leads to problems where there are long residence times and a lack of checking for the presence of pests. Systems have been devised for the early warning of insect presence by pheromone trapping or placing of bait bags. Continual stock rotation is vital for avoidance of problems. This chapter has focused on some of the specialist control procedures available for use when insect or mite populations are discovered, but the real solution to the problem lies in the devising of measures to avoid their establishment in the first place.

## 15.8 References

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## Microbiological environmental sampling, records and record interpretation

**J. T. Holah, Campden BRI, UK**

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**Abstract:** It is becoming more evident in the food industry that the prevention of cross-contamination from the processing environment is crucial for many ready-to-eat (RTE) foods. Cross-contamination is prevented by the implementation of suitable prerequisites, which have to be appropriately controlled. Environmental sampling plans, particularly for microorganisms, play a critical role in ensuring that such prerequisites are validated, monitored and verified as required. This chapter describes the role of the microbial environmental sampling plan, sampling strategies that can be implemented, sampling techniques that are suitable for the validation, monitoring and verification of surfaces, people, the air and water, and discusses practical sampling skills.

**Key words:** process development, troubleshooting, monitoring, validation, verification, processing environmental plan, swabbing, rinses, sponges, adenosine triphosphate (ATP), protein, sampling plans, transport fluids, neutralisation.

### 16.1 Introduction

#### 16.1.1 Reason for sampling the processing environment

Food manufacturers are encouraged to take all measures to ensure the safety and wholesomeness of their products. Contamination of food products can arise from the product itself via the raw materials or from the processing environment, including the structure, the equipment and services, the air and the operatives (Chapter 3). Whilst the control of raw materials and the product is controlled by the hazard analysis and critical control point (HACCP) plan, the control of the processing environment is via prerequisite programmes. Fundamentally, sampling of the processing environment is undertaken as part of the monitoring and verification of the prerequisite programme controls.

The control of some contaminants does not require sampling. For example, glass may be controlled by a physical inspection such that all glass



in the production area is examined for breakages prior to production. Metal is controlled by in-line magnets or metal detection whilst pest control is usually contracted out to commercial pest control operators who visit the plant approximately once per month. Sampling has been traditionally targeted to microbial contaminants, though sampling for allergen residues is now becoming common.

Effective management of environmental sampling will conform to company and customer requirements and satisfy the demands of international supplier audit programmes. In turn this will aid in the prevention of a loss of reputation or business and aid in brand protection. Within food safety law, environmental sampling can also support legal due diligence defences and help determine batch separation in the need for any product recalls.

Finally, environmental sampling can be used to detect changes that could give rise to pathogens, e.g. growth of general aerobic bacteria in the environment, or pathogenic bacteria themselves, prompting their control in the environment before they become a hazard in the food itself. Trend analysis of environmental sampling data over time can be used to continuously improve prerequisite management programmes whilst if environmental cross-contamination to the product does occur, enhanced and targeted environmental sampling can be used to determine the source of a pathogen in an outbreak/incident situation.

### 16.1.2 What to sample for

Environmental sampling has traditionally been undertaken to assess microbiological levels on surfaces, on people, in the air and in liquids. Microbiological sampling typically assesses the total number of viable microorganisms present in the sample to maximise the opportunity to detect whether a prerequisite is under control.

Sampling targeted at specific pathogens is undertaken to verify that the processes designed for their elimination or minimisation are in control and include, for example, *Salmonella* spp., *Listeria monocytogenes* and *Escherichia coli* O157:H7. Since it is expected that pathogens will be absent from samples, pathogen sampling is not a useful exercise to verify processes developed for broader microbiological control. Traditionally, sampling has also been undertaken for indicator organisms such as Enterobacteriaceae, which were thought to indicate the presence of a specific pathogen such as *Salmonella*. It is now believed that to verify the absence of a specific pathogen, sampling only for that pathogen is acceptable. Detection of the presence of indicator organisms such as Enterobacteriaceae may indicate, however, that conditions exist in the environment for a pathogen to survive or grow.

With the development of single use, rapid chemical detection systems in the mid to late 1980s, methods were developed to assess the cleanliness of

surfaces based on the detection of adenosine triphosphate (ATP – see Section 16.3.1) or protein (see Section 16.3.2). ATP and protein systems have been developed as a general measure of ‘soil’ residues, including both microorganisms and product residues, as they are constituent parts of many of the soils found in food processing, and are thus used as a measure of the performance of the cleaning process. Finally, and most recently, rapid chemical detection systems have been developed that allow the detection of allergenic residues on surfaces. These techniques allow the validation of the freedom of allergens following cleaning programmes that are used as a barrier between the production of allergenic and non-allergenic foods.

## 16.2 Sampling programmes and strategies

Environmental sampling is required in three phases or programmes of production:

1. Process development – to understand the influence of the processing environment on the process and to validate any prerequisite controls.
2. Routine hygiene sampling – monitoring and verification of the prerequisite programme controls.
3. Troubleshooting – a programme of additional sampling to establish cross-contamination sources and vectors.

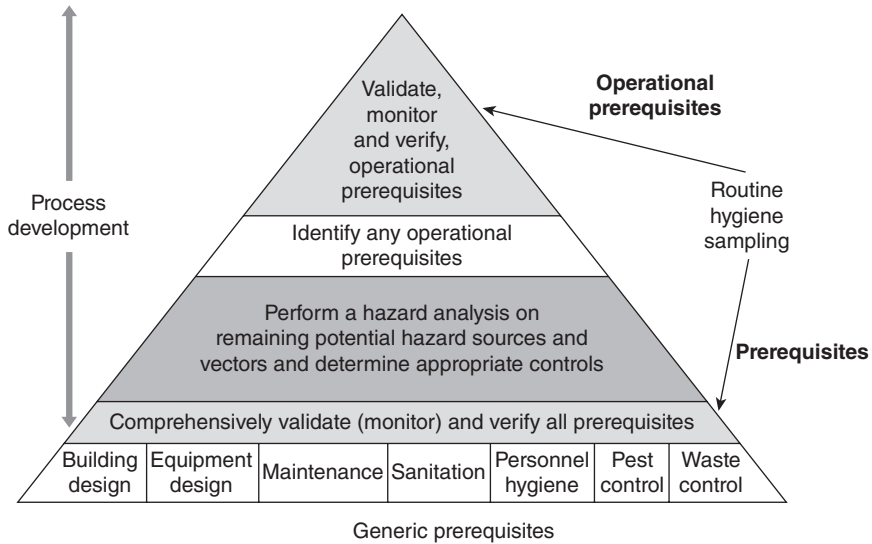
The roles of process development and routine hygiene sampling are illustrated in Fig. 16.1, which is in the format of a processing environmental plan (PEP) as discussed in Chapter 2. Within the PEP pyramid, process development is concerned with validating generic prerequisites, the hazard analysis of any remaining hazards, and determining and validating any subsequent controls. Routine hygiene sampling is initiated when the process goes into production and is concerned with the monitoring and verification of the previously validated controls.

### 16.2.1 Process development

Environmental sampling during process development is conducted on a new or changed process to (a) identify potential sources and vectors of contamination to the product, undertake a hazard analysis and establish appropriate controls and (b) validate whether procedures put in place to control the identified hazards are working.

The principles of how to undertake a PEP to assess sources and vectors of contamination have been established in Chapter 2. Environmental sampling to support process development, however, goes further than the PEP to better understand the processing environment and its potential influence on the product.





**Fig. 16.1** The relationship between process development and routine hygiene sampling with the PEP pyramid.

Many samples are usually taken during the process development phase and the data generated are often used to describe statistically the mean and range of microbial numbers or other hazard levels typically found at that specific site or after that specific process. When a process or an environment is changed, the influence this has on the statistical distribution of microbial numbers should be re-evaluated. Because of the statistical importance of data gathering at this stage it is often best practice to take statistical advice.

Some assessments typically undertaken using environmental sampling in process development are indicated below.

- Determining the build-up of microorganisms on product contact surfaces to ascertain when levels are such that they could be detrimental to product quality/safety. This also determines when cleaning and disinfection are necessary.
- Determining the required frequency of in-production cleaning and its efficacy.
- Assessing the relationship between microbial and non-microbial detection systems for sanitation programme performance testing.
- Identifying areas of equipment that are particularly difficult to clean.
- Identifying the requirement for periodic in-depth cleaning and its efficacy.
- Determining the level of microorganisms in the water supply and how this varies with change in supply, season and weather conditions.

- Determine the need for on-site water treatment systems.
- Assessing the levels of microorganisms on ingredient packaging, utensils, etc., entering high-risk areas and the necessity for any barrier ingredient packaging/utensil surface decontaminating techniques.
- Determining the level of microbial build-up on handwash station surfaces, the requirement for cleaning and disinfection and its frequency.
- Assess the impact of any cross-contamination to the user of the environment from handwashing and drying techniques.
- Determine the build-up of microorganisms on the surface of gloves worn by personnel and establish their change frequency.
- Determining the requirement for environment supply air to be microbiologically controlled and the influence of season.
- Determining point sources of airborne microorganisms (e.g. tray washers, cleaning, processes).
- Establishing air flow patterns around production lines under all production times and conditions.

Following the incorporation of generic, best good manufacturing practice (GMP)/good hygienic practice (GHP) prerequisite practices, and the adoption of controls for specific sources and vectors identified during the PEP process, control practices can be validated. Some controls typically validated using environmental sampling techniques include validating:

- the efficacy of the mid-shift, end-of-production and periodic sanitation programme;
- the efficacy of water treatment systems for process waters;
- the efficacy of water, steam or UV-based disinfection systems for the control of utensils/ingredient packaging at low-/high-risk barriers;
- the efficacy of washroom cleaning and disinfection;
- the efficacy of handwashing and handrub agents;
- the performance of in-house or contract laundry services;
- the efficacy of footwear disinfection systems;
- the efficacy of air control procedures (e.g. air barriers, air filtration);
- the performance of air handling systems (e.g. over-pressures, directional flow).

For some prerequisites, validation may be undertaken to ensure that prerequisite controls are performing to international, national or industry standards. This is likely to apply to the efficacy of water treatment systems or contract laundry services as noted above. Some prerequisites, however, have to be validated to provide a target value that may be unique to individual food manufacturing sites.

For example, cleaning targets are unique to each food manufacturing process as the food product, degree of soiling, food production equipment and cleaning programmes are all unique. A typical approach would be to

assess the level of microorganisms or ATP present on a surface after a series of 5–10 sanitation programmes in which the sanitation programme is carefully controlled (e.g. detergent and disinfectant concentrations are correct, contact times are adhered to, water temperatures are checked, pressure hoses are set to specified pressures, sanitation schedules are followed and the correct number of cleaning operatives and cleaning time was available). The mean result will provide an achievable standard (or standards if specific areas or food contact materials differ significantly in their cleanability) which can be immediately used and can be reviewed as subsequent data points are obtained from trend analysis studies in the future. In this example a value of 300 relative light units (RLU)/swab could be set and any value recorded above, for example, the target plus 25% (375), would be unacceptable and initiate corrective actions, i.e. re-cleaning. A review of the standard would be required if the food product, process, equipment or the sanitation programme were changed.

### 16.2.2 Routine hygiene sampling

Routine hygiene sampling is concerned with the monitoring and verification of prerequisites and operative prerequisites. Monitoring (see Section 16.3) can only be undertaken by rapid methods and in the context of this chapter is limited to ATP and protein technologies. Monitoring of prerequisites is unlikely to be undertaken for food safety reasons (otherwise the prerequisite would be an operational prerequisite) but could be undertaken for, for example, economic reasons. For example, it is common that within a cleaning and disinfection programme, an ATP reading is taken immediately after the cleaning phase and the result analysed before disinfection occurs. Disinfection is only initiated after surfaces have been appropriately cleaned, saving the cost of cleaning and disinfection chemicals if ATP was used for verification of the cleaning and disinfection programme as a whole and re-cleaning and disinfection prior to production was thought necessary.

Monitoring operational prerequisites is likely for food safety reasons. For example, where cleaning between an allergenic production run and a non-allergenic run is established as the major control of cross-contamination, monitoring of the cleaning efficacy is required on each cleaning occasion. If possible, food manufacturers try to correlate cleaning to below the level of detection of an allergen test, with a target value of a rapid hygiene method such as ATP. An ATP target value, which is cheaper and faster than an allergen test, then becomes the monitor of the cleaning programme to indicate the likely removal of allergen residuals.

Verification of prerequisites can be undertaken on an individual basis or on a collective basis where single analyses can be used to verify the performance of a number of prerequisites. It is likely that operational prerequisites will be verified on an individual basis.

*Monitoring and verification of individual prerequisites*

The choice of sampling site must reflect and support the prerequisite/operational prerequisite control. As a general rule, microbiological sampling should be targeted to the site at which the most likely chance of microbial presence will occur.

For example, if sampling a piece of equipment is intended to verify cleaning, which is intended to remove microorganisms or debris that could affect subsequent food production runs, it is more sensible, and gives more confidence, to sample the points of the equipment that directly contact the product and that are difficult to clean, e.g. the shear edge, the 'gripper box' or the meat feed conveyor on a meat slicing machine. Sampling of the flat surfaces on the exterior of the equipment or the equipment framework could form part of an occasional hygiene assessment procedure to ensure that cleaning operatives are cleaning all exposed surfaces of the processing equipment.

In some cases it may not be possible to sample the optimum point likely to harbour hazards because of safety reasons, for example sampling blades or access to processes that may be interlocked, e.g. mixers with moving stirrers. Similarly, it is often not possible to enter into tanks and vessels or access pipework immediately after a given process. The fitting of sampling cocks may be possible but, unless hygienically designed and cleanable between samples, may lead to spurious results.

For verification purposes, the variability inherent to the sampling site should be kept to a minimum so that a better picture of the variability of the process can be obtained. Wherever possible, the sample point should be exactly the same, e.g. the shear edge on a meat slicer, though it may also be size related, e.g. a 100 cm<sup>2</sup> portion of a conveyor belt surface. Other factors to consider include the effect of time, day, season, batch, product ingredients and product process.

The frequency of sampling is related to risk and should be derived from the relevant PEP hazard analysis study. As a general statement, the following frequencies may be helpful:

- The sampling of an operative prerequisite to **monitor** the process, for example an assessment of the efficacy of end of production cleaning by ATP to indicate freedom of an allergenic residue, is likely to be required every time the process is undertaken.
- The sampling of an operational prerequisite to **verify** the process is likely to be required less frequently than for monitoring purposes. This could be undertaken, for example every few days or every week.
- Routine **verification** of prerequisites is required even less frequently and could be undertaken every week or every month.

Sample testing is expensive, especially for pathogens the identification and enumeration of which may need to be contracted out. For some factories with identical process lines, it may be possible to reduce sample numbers

**Table 16.1** Schematic sampling strategy

	Line	Filling hopper	Weigh scales	Conveyor
1	1	*	*	*
	2			
	3			
2	1	*		
	2	*		
	3	*		
3	1			
	2	*	*	*
	3			
4	1		*	
	2		*	
	3		*	
5	1			
	2			
	3	*	*	*
6	1			*
	2			*
	3			*

\* Point of sampling.

by devising suitable sampling plans. For example, a sandwich manufacturer packs prawn (shrimp) sandwiches as the last sandwich product prior to end-of-production cleaning and as such, the end-of production clean must be validated to ensure freedom of prawn allergen. The freedom of allergenic residues has been correlated with a target ATP reading for subsequent cleaning verification. There are three sandwich lines consisting of depositing hoppers, weigh scales and conveyor belts. It may be possible to reduce the sample number from nine samples per day (three hoppers, three weigh scales and three conveyor belts) to three per day by adopting the sampling strategy shown in Table 16.1. Using this sampling strategy at least every similar piece of equipment or every line is sampled after every end-of-production clean.

One problem with sampling strategy is that it has been suggested that it may reduce the efficacy of the sanitation programme if cleaning operatives 'know' where sampling is to be undertaken so that only those points are thoroughly cleaned. If, however, the sampling is 'unpredictable' to the cleaning operatives, all lines and all equipment have to be cleaned to the same degree every day as they will be unsure as to where sampling will next be undertaken.

The use of composite samples is another technique to reduce sample numbers analysed and in the above example it would be possible to sample all pieces of equipment after every day and pool either all filling hoppers,

etc., or the line samples. This again would lead to the analysis of three samples together instead of nine (i.e. pooled hoppers, weigh scales or conveyors or pooled lines 1, 2 and 3). This has advantages and disadvantages. If the sampling is to detect pathogens, the sampling of the whole line and the analysis of the composite sample, by maximising sample size, may increase the chance of detection. If the sampling is for the verification of an operational prerequisite, e.g. ATP analysis to indicate freedom of an allergen, the compositing of results may prevent the trend analysis of the cleaning efficacy for individual equipment/lines.

By the use of sampling strategies or the compositing of samples it is also possible to increase the range of sampling activities whilst still providing meaningful results. Again in the above example, the six samples saved by strategy or compositing could be used for the assessment of another process, etc.

#### *Verification of collective prerequisites: sampling strategies*

Within the processing environment pathogens are (hopefully) sporadic and present in low numbers. They are therefore difficult to find! A number of sampling strategies have thus evolved to maximise the chance of detecting a pathogen in the processing environment at an early stage such that its presence can be controlled prior to it becoming a significant risk to product contamination. Three common strategies include:

- collector sites;
- zonal approach;
- barriers approach.

It is much easier to detect the potential presence of pathogens initially by sampling either an area in which they will eventually collect, e.g. the drains after the production environment is cleaned down, or by sampling a utensil which itself covers a large surface area of the production environment, e.g. a cleaning brush or pad, or via transport systems that move around the processing area, e.g. trolley wheels. Similarly, when detecting airborne microorganisms, sampling within known air streams in processing environments is more likely to detect microorganism than sampling stagnant air zones. Sampling the fins of motors and air filtration inlets within the processing area also maximises detection for those pathogens that may survive such environmental conditions, e.g. *Salmonella* or *Cronobacter*. Such sampling points are known as collector points.

The detection of a pathogen on a collector site does not necessarily indicate that the sampling site is contaminated; it suggests that a pathogen somewhere in the environment has been 'collected'. If a pathogen is detected on a collector point, further pathogen sampling must be undertaken to try and determine the source of the contamination. Collector points also offer the possibility of verifying multiple prerequisites in an area, via a single

sample, all of which are each involved in controlling pathogens in their own process. In this sense, the absence of pathogens suggests that all such prerequisites are in control.

The zonal and the barriers approach are environmental sampling strategies that have been developed in the USA and the UK respectively to fit into the legislative and customer requirements of these countries. The zonal approach is typified by the detection of *Salmonella* in low-moisture foods and has been detailed in a guidance document from the Grocery Manufacturers Association of the USA (GMA, 2009). A zonal approach is adopted as follows:

- Product.
- Zone 1 – product contact surfaces within the Primary *Salmonella* Control Area (areas of the plant in which product is handled prior to initial packaging and following any product heat treatment).
- Zone 2 – non-product contact surfaces adjacent to or within close proximity to product contact surfaces within the Primary *Salmonella* Control Area.
- Zone 3 – for non-product contact surfaces more distant from product contact surfaces in the Primary *Salmonella* Control Area and process areas outside the Primary *Salmonella* Control Area.
- Zone 4 – for areas outside the process area (e.g. employee entrance, locker room, warehouse, loading dock).

Product and product contact surfaces are rarely sampled. The main focus for environmental sampling, undertaken during production, is Zone 2, which is sampled, e.g. daily, followed by Zone 3 sampled weekly and Zone 4 sampled monthly. The concept is that *Salmonella* moves from Zone 4 towards the product in a ‘progressive’ manner such that detection of the organism in areas away from product contact surfaces allows the organism to be controlled at an early stage, potentially before it becomes a risk to product. Identification of *Salmonella* in, for example, Zone 3 leads to a ‘seek and destroy’ programme, in which identification of the organism’s source and its control are paramount, and leads to an increase in sampling in the next zone (Zone 2). If *Salmonella* is found in Zone 2, sampling of Zone 1 may be initiated. Sampling in all zones is increased if abnormal activities are occurring in the environment, e.g. building work. The basis of the model is thus source dependent, does not actively consider vectors (other than distance from product contact areas) and assumes that if there is no pathogen source, there is no product cross-contamination.

The barrier approach has been developed in the UK primarily to control *Listeria* in ready-to-eat (RTE), chilled foods. The philosophy for the safe manufacture of RTE foods is that all handling of the product, prior to it entering its initial packaging and after its decontamination process, e.g. cooking or washing, must be undertaken in a segregated high-hygiene

(high-care or high-risk) area. A series of barriers is provided at entrances to the segregated area that allows the entrance of products, packaging, utensils/cleaning chemicals, people and the air and the exit of packed product and waste, whilst preventing the entrance of pathogens. If a pathogen moves across these barriers and enters the high-risk area, its harbourage, growth and spread is prevented by attention to hygienic design of equipment and the environment and by keeping the environment as dry as possible during production. Following production, a cleaning and disinfection programme is designed and initiated to ensure the removal from, or destruction of, pathogens in the high-hygiene area.

Environmental sampling follows this three-phase philosophy. Firstly, samples are taken around the barriers during production to verify the barriers' effectiveness. If pathogens are found, focus is on the adequacy and management of the barrier controls. Secondly, samples are taken at collector points (sources) or transmission vectors (see Chapter 2, which could be product contact surfaces, e.g. utensils) during production to verify the absence of pathogen sources and the control of product vectors. If pathogens are found then, as for the zonal approach, a 'seek and destroy' programme is undertaken. Thirdly, following the cleaning and disinfection programme, food contact surfaces are sampled to verify the effectiveness of this sanitation programme. All samples following sanitation should be negative, but if pathogens are found, the adequacy and management of the sanitation programme is assessed together with a 'seek and destroy' (John Butts, Land O'Frost, personal communication) programme to identify the pathogen's source. Finally, no detection of pathogens is undertaken in areas where raw products are processed (pathogens would be expected in these areas) and the barrier sampling approach is always complemented by the analysis of the food product for pathogens.

It is difficult to compare and contrast the zonal and barrier approach as both have evolved to meet the legislative and political requirements in the regions in which they are practised and it is unlikely that the alternative approach (i.e. zonal in Europe or barriers in the USA) would meet these region's needs. What is critical, however, is that for the manufacture of RTE foods, all efforts should be made to prevent pathogens entering high hygiene areas (post-product decontamination and prior to initial packaging) and an effective environmental sampling programme should be established to verify the effectiveness of any prerequisite controls designed to prevent such entry or to effectively decontaminate the area.

### *Trend analysis*

As part of the environmental sampling plan review procedure, it is good practice to look how the prerequisite controls are performing over a defined time period (weekly, monthly, quarterly, etc.) as individual sample results are only an estimate of what is happening at one specific time period only. This may be to ensure that the prerequisite remains within control, to



reduce the variation within the process or, as should be encouraged, to try to improve the prerequisite performance, e.g. sanitation programmes.

An assessment of the performance of a process with time, or trend analysis, can be undertaken simply, by producing a graphical representation of the results on a time basis, or can be undertaken from a statistical perspective using statistical process control (SPC) techniques.

Graphical representation is the most widely used approach for environmental assessments. It is used primarily as both a record of the environmental sampling results and for trend analysis and gives some indication of whether the prerequisite process overall is performing within specification. It can be accomplished very easily using paper records or wall charts or can involve the use of simple software packages, for example ATP hygiene monitors, often have an optional software package in which results can be directly downloaded into computer-generated trend analysis graphs. The output from these graphs can also be used as a visual record so that operatives responsible for the process can see how they are performing. The use of SPC techniques to implement either a reduction of the variability within the process or an improvement in the process's performance is relatively rare in the food industry, but could perhaps be appropriate for some operational prerequisite processes.

### **16.2.3 Troubleshooting in sampling strategies**

Troubleshooting is a procedure that is typically undertaken in response to an unacceptable product or environmental sample result, to help establish its cause (Holah, 1999). The level of response is related to the nature of the unacceptable result and the associated risk to food safety. Some typical responses are as follows:

- Failure of an ATP cleaning monitor (see Section 16.3.1). The use of a validated rapid monitor such as ATP analysis could be undertaken to ensure that effective cleaning has been undertaken between one allergenic production run and a subsequent non allergenic production run. Repeat cleaning programme and reassess surface cleanliness levels. Resume production following a successful cleaning programme. Review any reason for the initial cleaning failure.
- High total viable count (TVC) on a prerequisite verification. Check the prerequisite's operating records and resample. Identify whether it is a frequent failure or an occasional high count. If frequent, revalidate the prerequisite and retrain the operatives.
- High indicator organism count. In a dry food factory this may indicate the presence of water, which has led to microbial growth. Any evidence of water leakage should be established (and fixed) and additional sampling for pathogens should be undertaken as they may have been introduced and/or multiplied.

- Pathogen in the environment. Decontaminate the area. Determine whether there have been any changes in the environment or the process that could have introduced a pathogen into the environment, e.g. change in raw materials supply, building work, introduction of second-hand equipment, water leaks. Assess any routes of transmission that could have transported the pathogen from its point of identification to other environmental areas or the product. Increase environmental samples for pathogens in these areas. Assess the necessity for any enhanced product sampling. Increase environmental sampling for a time period to ensure that there is no persistent pathogen presence.
- Pathogen in the product. This is the most serious result and triggers actions to the products produced that may have become contaminated and a root cause analysis to establish the nature of the problem. Product traceability and the need for a recall are outside the scope of this chapter, but the following is an approach to a root cause analysis:
  - *Is the problem real?* How much confidence do you have in the microbiological evidence and the detection techniques used? Has more than one laboratory confirmed the presence of the organism in the product? Is the pathogen detected the same as the laboratory positive control strain?
  - *What is the scale of the problem?* Has more than one sample been taken, is the problem within a batch, between batches or across a product range?
  - *Has the process or recipe been changed?* Is there a new source of raw materials or the use of different raw materials? Are any single raw materials implicated?
  - *Has the problem occurred before and was it solved?* Are there any historical records of previous incidences and their resolutions – these show the usefulness of post-mortem records following pathogen detections in product and subsequent investigations. Has the pathogen been genetically fingerprinted – is it the same as previous isolates?
  - *Are microbiological reduction processes for product (e.g. ovens), in control?* This will involve examining production records for non-microbiological data, e.g. temperatures and times and/or the checking of microbiological process establishment data.
  - *Are environmental prerequisites (e.g. bootwashing, handwashing, air filtration, sanitation programme) in control?* Do other general microbiological verification records show high counts that could indicate prerequisite failures?
  - *When the production process is followed from preparation to finished product dispatch, where is product contamination first encountered?* Once a product becomes contaminated, the product itself will spread the contamination downstream.

- *When during the production batch is product first contaminated?* Contamination at the beginning of production is related to, for example, raw materials, failures of microbiological control processes or gross environmental contamination levels. Contamination first arising late in the production batch is usually related to sanitation programmes not operating properly and leaving microbial residues that grow throughout the production period to a level that will infect, and is detectable in, the food product, or to areas of poor hygienic design which again can harbour similar microbial residues. This may also indicate that production runs are inherently too long in terms of product safety and quality.
- *If sampling indicates an item of equipment that may be a contamination source, have discussions taken place with engineers so that the equipment can be fully dismantled for inspection?* Note: it is often helpful to combine the microbiological sampling results with a plan of the processing area to more easily see any trends or potential routes of contamination.

When an occurrence of microbial contamination occurs in either the environment or the product, other steps are also taken (e.g. the total sanitation of the whole processing environment) such that the source of microbial contamination may never be discovered before it is deemed safe to start production again. It is especially important, therefore, to increase the level of routine hygiene testing immediately after such incidents to:

- increase confidence that the process is operating within control limits;
- or
- provide additional evidence of the potential source of the problem so that it can be prevented in the future.

Once in control, the elevated sampling level can be gradually reduced to that of normal prerequisite verification.

### 16.3 Sampling methods: monitoring surfaces

Surfaces include all hard inanimate surfaces and are typified by food processing equipment, cleaning equipment and environmental surfaces (floors, drains, walls and ceilings). Food processing surfaces can be further subdivided into open and closed surfaces. Open equipment surfaces are defined as immediately accessible for sampling, or can be made easily accessible by dismantling, e.g. conveyors, hoppers and formers and cover the majority of surfaces to be sampled. Closed surfaces equipment surfaces are generally inaccessible for sampling, or can only be made accessible with difficulty, e.g. liquid handling systems.

Surface monitoring methods allow an assessment of the 'hygiene' of the surface in a time frame to allow process control. Historically, monitoring of

surfaces could only be undertaken by human senses, i.e. touch or smell. For example, visible assessment of surface cleanliness is undertaken to assess whether surfaces have been cleaned sufficiently to allow subsequent disinfection. It should be clearly stated that further monitoring or verification sampling of an area that is visibly dirty to assess, for example, whether a cleaning programme has been undertaken, is both unnecessary and could be misleading.

Since the mid-1980s, a number of methods have been developed to allow an assessment of surface hygiene to a level more sensitive than visible cleanliness, including the detection of ATP and proteins. These techniques are known as rapid methods and are able to generate a result within approximately 20 minutes. No technique is presently available which will allow the detection of specific microbial types within this time frame.

A range of surface and other environmental sampling techniques were reviewed by a Campden BRI working party of food and environmental sampling kit manufacturers (Holah and Hall, 2004).

### **16.3.1 ATP**

The most popular and established rapid hygiene monitoring technique is that based on the detection of ATP by bioluminescence and is usually referred to as ATP testing. ATP is present in all living organisms, including microorganisms (microbial ATP), in a variety of foodstuffs and may also be present as free ATP (usually referred to together as non-microbial ATP). ATP detection techniques are based on the reaction of ATP with luciferin (substrate) and luciferase (enzyme), such that for each molecule of ATP present, one photon of light is emitted. The photons are then detected by a luminometer and recorded as RLUs, which are arbitrary values. The reaction is very rapid and results are available within seconds of placing the sample to be quantified in the luminometer.

The amount of light produced is directly related to the level of microbial and non-microbial ATP present in the sample and is often referred to as the 'hygienic' status of the sample. It is possible to differentiate between the measurement of microbial and non-microbial ATP but for the vast majority of cases, the measurement of total ATP (microbial and non-microbial) is preferred. This is because surface hygiene samples are generally taken as a monitor of the success of the cleaning and disinfection programme. As there is more inherent ATP in foodstuffs than in microorganisms, the measurement of total ATP is a more sensitive technique to determine remaining residues. Large quantities of ATP present on a surface after cleaning and disinfection, regardless of their source, is an indication of poor cleaning and thus a contamination risk (from microorganisms or materials that may support their growth).

ATP detection is now a commodity in the food industry and a number of companies produce a variety of hygiene monitoring systems consisting



**Fig. 16.2** A number of commercial kits are available for the rapid detection of ATP and protein. These kits comprise swab sticks, containing swabs to sample, for example surfaces and the necessary reaction fluids to initiate the chemical detection process, and a hand-held instrument to detect the light or colour output of the detection process.

of some or all of the following: a sampling device, reaction chemicals, a combined 'one-step' sampling and reaction device, a luminometer, calibration devices and a range of software options for data storage and analysis (Fig. 16.2). Most systems are swab-based and are used to ascertain the level of ATP present on surfaces though some manufacturers produce kits that allow the detection of ATP from water, the air and foodstuffs. The usefulness of ATP test kits has to be established at the factory level where differences in food soiling and cleaning chemicals may affect the test performance (the ATP reaction may be quenched by certain types of disinfectants/cleaning agents as well as some food ingredients). The luminometer must also be regularly calibrated.

### 16.3.2 Protein analysis

Techniques have also been developed which monitor protein concentrations as markers of surface contamination remaining after cleaning. Some of these methods have been adapted in a swab-based format for detection of protein on a surface. Such rapid hygiene tests indicate the presence and quantity of protein residues by a colour change reaction in a time frame (approximately 10 minutes) that allows an element of control of cleaning and disinfection programmes (Fig. 16.2).

Commercially available surface protein detection kits are based on, for example, the Biuret-type reactions or protein error indicator reactions. In the Biuret reaction, under alkaline conditions the peptide bonds of proteins reduce the copper II ions ( $\text{Cu}^{2+}$ ) to copper I ions ( $\text{Cu}^+$ ) which then form a purple complex with bicinchoninic acid (BCA). Following swabbing, the colour change is recorded after a 10 min incubation period at ambient temperature (15–25°C). A colour change from green to either grey or purple indicates a positive result. Test kits based on protein error chemistry contain protein error indicators (pH indicators whose  $\text{pK}$  value is displaced in the presence of protein, e.g. tetrabromophenol blue) and a buffer formulated such that the presence of protein gives rise to a colour change. Following swabbing, an instant colour change from yellow to green or blue indicates a positive result, indicating that the surface is contaminated.

As with ATP, the usefulness of protein test kits has to be established at the factory level where differences in food soiling and cleaning chemicals may affect the test performance (the chemical reactions may be quenched by certain types of disinfectants/cleaning agents as well as some food ingredients). They are generally cheaper in use than ATP-based systems as the end point of the tests is a visible colour change rather than a signal that is interpreted by an instrument, e.g. light output measured by a luminometer.

## **16.4 Sampling methods: validation and verification of surfaces**

Surface validation and verification methods validate and verify the performance of surface hygiene controls. Primarily these have been microbiologically based and involve the capture, enumeration and/or identification of surface adhered microorganisms. There are two principal methods of removing microorganisms from open surfaces and both use frictional and/or adhesive forces. These are entraining them in a fibrous matrix (swab or sponge) rubbed over the surface, from which they are subsequently released for detection or 'imprinting them into a solid agar base (contact plate) pressed onto the surface, from which colonies become directly visible following incubation. General or specific media can be used to detect either total aerobic or anaerobic microorganisms, indicator organisms or pathogens.

Rinses are undertaken primarily for the sampling of enclosed equipment, which are difficult or impossible to access with swabs or wipes, where the frictional forces of rinsing solutions can be used to flush microorganisms to sampling devices. As an alternative to rinsing, some manufacturers prefer to verify the efficacy of the cleaning-in-place (CIP) programme by directly sampling the product, usually from the rinse water/product interface or the first batch of product produced. More recently swabs, sponges and rinses have been used to assess allergen levels.

The larger the surface area assessed, the more accurate the general contamination estimate and/or the greater the chance of detecting a specific pathogen. With increasing sampling area, however, the number of microorganisms captured will increase, producing counts of microorganisms that are excessive for the purpose. Large swabs (typically sample an area of  $15 \times 15 \text{ cm}^2$ ) thus usually sample surfaces that are potentially contaminated with higher levels of microorganisms, whereas surfaces that are more minimally populated are sampled with wipes or sponges ( $30 \times 30$ ). Small swabs ( $5 \times 5 \text{ cm}^2$  or less) are traditionally used to sample small, difficult to clean areas. There is also the assumption that if the most difficult areas have been effectively cleaned, then all general surfaces should also be clean. Templates of various sizes are available to help in judging the sizes of areas to be used and these are useful training tools, though they are not recommended, however, for routine surface assessment. The optimum technique to use has to be established at the factory level as all factories have different surface microbial communities at different populations.

The assessment of general cleaning performance in 'dry' food manufacturing is usually undertaken by sensory evaluation only as total removal of all visible debris is rarely achieved (i.e. little need for analysis beyond visual cleanliness) and microbial growth is controlled by low available water levels on surfaces. For some operations, however, it may be necessary to sample the environment for specific pathogens, for which wipes are recommended. It is essential, however, that if wet wipes are used, surfaces are totally dried prior to production.

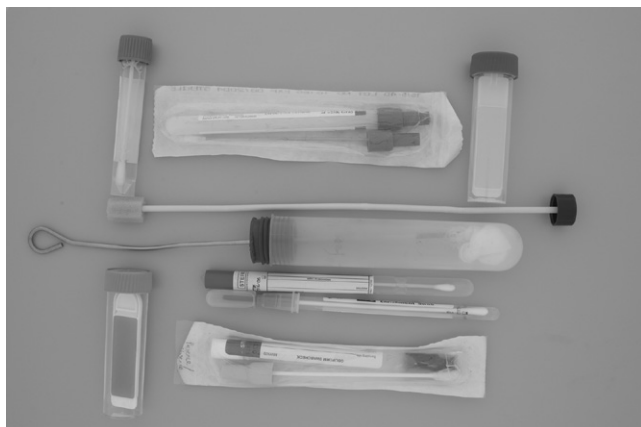
For the sampling of larger, indeterminate areas, sampling the dust collection bag in cleaning or extract vacuum systems or sampling the coarse air intake filters into various process equipment, e.g. coolers and dryers in dry food processing areas can also be undertaken. Alternatively, waste product (e.g. the product 'dust' that is collected by a slicing or cutting operation), may be sampled as an indicator of the hygienic status of the equipment during its period of operation. This technique is particularly used for the detection of pathogens as it is a useful way of sampling a large area of a machine that is difficult or unsafe to access for direct assessment. Obtaining dust or product residue samples is concerned with the use of good aseptic technique and the correct use of sampling strategies. Dust or product residues can be collected into any sterile container (e.g. plastic bags or plastic disposable sample bottles), using sterile utensils (e.g. sampling spoons or scoops).

Wherever possible, the principles of ISO 18593:2004 (Anon, 2004) should be followed for swab and contact plate methods.

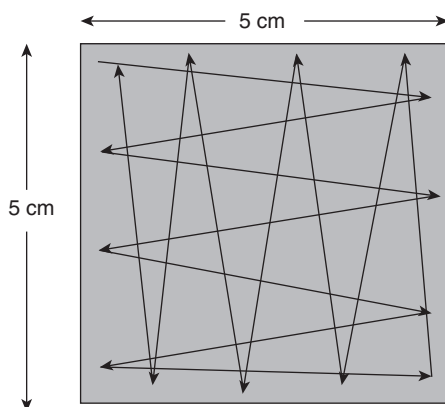
#### **16.4.1 Swabs**

Swabs consist of a thin plastic or metal stick with a fibre matrix bonded to its base (Fig. 16.3). If the surface to be sampled is wet, the swab is moved





**Fig. 16.3** Swab sticks are usually purchased commercially but can be home-made for a specific purpose, e.g. the metal swab in the centre of the figure which was used to swab inside pipework. Swabs may have liquid or solid transport solutions. Two contact plates are also shown which have different (coloured) agars for detecting generic or specific microorganisms.



**Fig. 16.4** Suggested sampling plan for swabs, together with the continual rotating of the swab in the fingers to allow the adsorption of sampling fluid into all parts of the swab matrix.

across the surface, backwards and forwards whilst rotating the stick (Fig. 16.4), such that microorganisms are released from the surface and fluid is drawn into every part of the matrix. If the surface is dry the swab is pre-wetted before application using a suitable sterile diluent or the swab neutralising and transport fluid. After the swabbing process is complete, the swab is either returned to its individual container and evaluated in a short time period (less than an hour) or placed into a sample bottle, containing a suitable neutralising and transport fluid, such that the stick touches the



lip of the sample bottle about half way down its length. The stick is then broken, using the lip for leverage, and the bottle sealed. (Note: swab stick breaking should be undertaken away from the product to prevent accidental contamination.)

The microorganisms collected in the swab can be enumerated at a gross level by inoculating the surface of agar plates by rolling the swab gently over the surface and incubating the plates. More usually, the swab and swab neutralising/transport fluid are vortexed for 30 seconds and small (1 ml) aliquots removed for enumeration via dilution series. Alternatively after vortexing, particularly for pathogens in which their presence or absence is being evaluated, the whole contents can be decanted into appropriate media.

Swabbing is subject to a degree of variability, e.g. the pressure applied, the degree of rotation, the time of sampling and the area of sampling, though this can be minimised through sampling operative training, e.g. the use of sampling quadrant templates. The ability of a swab to sample an attached microbial population has been examined by Holah *et al.* (1988) who established that swabs typically enumerate approximately 50% of surface adhered microorganisms over the range of surface populations likely to be found within food processing environments.

#### 16.4.2 Wipes and sponges

Wipes and sponges follow a similar format to swabs except that they are designed to sample larger surface areas (Fig. 16.5). Wipes and sponges,



**Fig. 16.5** Wipes are available in a range of sizes dependent on the size of the area to be sampled. Small areas are sampled with sponges attached to a stick support. Large areas are sampled with large sponges which are hand-held, with a sterile glove that is supplied with the sampling kit.

pre-moistened if required, are moved across the surface as aseptically as possible (e.g. using sterile gloves or tweezers or holding the sponge with its sterile outer packaging) in as standardised way as possible (which should be recorded), similar to that identified in Fig. 16.2. Microorganisms are recovered by placing the wipe or sponge into a sterile bag containing neutralising/transport fluid and stomaching for a predetermined time (a minimum of 30s). Alternatively, the wipe or sponge can be aseptically squeezed and wrung in a predetermined (and recorded) fashion to release captured cells and the sampling fluid. Aliquots of the fluid are then removed for serial dilution or other appropriate evaluation.

### **16.4.3 Contact plates**

Contact plates consist of an agar surface which is pressed onto the surface to be sampled, rocked slightly from side to side, removed and incubated at an appropriate temperature (Fig. 16.3). They are commercially available, commonly referred to as 'dip slides' or can be made in-house by filling small sterile dishes (e.g. Rodac™) plates or Petri dishes, consistently, with a known volume of agar. When used on some surfaces, agar debris left on the surface during sampling will have to be removed, e.g. with an alcohol wipe, to prevent microbiological growth associated with such nutrient debris.

Contact plates have many advantages; they are very simple, easy to use, need no preparation (when purchased commercially) and are capable of detecting a range of microorganisms by selecting appropriate agar recipes. They also require little or no laboratory facilities other than an incubator, though the waste disposal route of the incubated culture plates should be considered. Contact plates, however, can only be used on reasonably flat accessible surfaces, the surface area of sampling is limited and they are only suitable to assess surface populations in a range that can be accurately counted on their surface, i.e. 10–100 colonies.

### **16.4.4 Rinses**

The principle of the rinse technique is to use an appropriate sterile sampling fluid to flush microorganisms from food contact surfaces. The efficiency of the process will depend on a number of factors including the accessibility and wettability of the surface and the degree of energy incorporated into the technique (sampling a large filling machine by rinsing under gravity is likely to release fewer microorganisms than sampling a container by shaking a rinse solution within it). If accessibility precludes the use of a separate rinse solution following the completion of the CIP programme, the final CIP rinse solution can be sampled directly from where it flows to drain or via specific sampling cocks.

Rinsing has the advantage that large surface areas are covered. In addition, the rinse fluid can be filtered through a membrane filter to

concentrate released microorganisms and so improve technique sensitivity. Rinses cannot, however, pin-point specific areas of contamination, particularly when the final rinse solution from the CIP programme is sampled. If contamination is identified, dismantling of the equipment may be required together with further examination of specific sites by swabbing.

#### 16.4.5 Allergens

Methods of analysis for detecting allergens are based either on the detection of a specific protein (virtually all known food allergens are proteins) or the detection of DNA (Arrowsmith and Brown 2009). These test may be quantitative (measuring the amount of allergen) or qualitative (indicating whether the allergen or allergenic ingredient is present above a certain level or not). The most widely available protein detection methods are based on immunoassays, either in the format of a 96 well plate or a dipstick. Immunoassays include the sandwich enzyme-linked immuno sorbent assay (ELISA), in which the analyte becomes sandwiched between two layers of antibody and the competitive inhibition ELISA, in which there is competition for antibody between allergen in the sample and allergen added in the assay. ELISA tests are very sensitive and can detect allergens or allergenic ingredients at low mg/kg levels. Quantitative ELISA tests compare the colour measured in the wells with the colours in a series of wells containing a known range of standards. In qualitative ELISA, a standard solution containing a known concentration of allergen is assayed alongside the sample and the result is recorded as above or below the standard. With dipsticks, a liquid sample is drawn through a membrane containing immobilised antibodies that capture the analyte and generate coloured lines. The coloured lines indicate the presence or absence of the allergen and the validity of the test and, though not as sensitive as quantitative ELISA, they can produce qualitative and semi-quantitative results.

The detection of DNA can be used as a marker of the presence of an allergen and generally involves the use of the polymerase chain reaction (PCR). PCR analysis comprises the target DNA extraction and purification, the amplification of a specific piece of DNA and the detection of amplified product. The PCR product is then compared with DNA fragments of standard size on an electrophoretic gel such that if the sample contains DNA from the allergen of interest, a band of a certain size will be seen in the gel. The result is therefore qualitative; either a band is present or not.

A number of test kits are now available that can be used or modified for the detection of allergen residues on surfaces, including the detection of celery, cereal (containing gluten), crustacea, egg and egg white, fish, lupin, milk (caesin,  $\beta$ -lactoglobulin), molluscs, mustard, nuts (almond, brazil, cashew, hazelnut, macadamia, pecan, pistachio, walnut), peanut, sesame,

soya and sulphite. Allergen detection kits can be sourced from a number of companies including:

- Tepnel: [www.tepnel.com](http://www.tepnel.com)
- R-Biopharm: [www.r-biopharm.com](http://www.r-biopharm.com)
- Neogen: [www.neogen.com](http://www.neogen.com)
- ELISA Systems: [www.elisas.com.au](http://www.elisas.com.au)
- HAVen [www.hallmarkav.com](http://www.hallmarkav.com)

Many food manufacturers have adopted the philosophy of validating their allergen cleaning programme using the appropriate specific allergen test kit and then verifying the performance of the cleaning and disinfection programme on a day-to-day basis with an alternative hygiene monitor, e.g. ATP. For this to be an acceptable practice, the validation of the cleaning programme must be undertaken using both the allergen test kit and the hygiene monitor. In this case the validation seeks to demonstrate freedom of allergenic residues after cleaning and a positive relationship between freedom from allergens and freedom from the target for the hygiene monitor (ATP, protein, etc.). At this stage it is not possible to state that freedom from allergenic residues as demonstrated by sample results lower than the detection limit of the test kit equates to freedom from an allergenic effect in the final consumer from product produced from such surfaces. In the absence of any other information, however, allergen cleanliness as determined by results lower than the detection limit of the test kit should be the target of the sanitation programme.

## 16.5 Sampling of personnel

Personnel are both reservoirs (sources) and vectors of microbial contamination to food product. The reservoirs of organisms from the body can be divided into two broad categories; those found on the external surface, which can be further divided into two categories; transients and residents, and those found in the alimentary tract and which are excreted in the faeces. Validation of carriage of pathogens or the freedom of secretion of pathogens following illness can be undertaken via stool samples, but this is primarily undertaken by medical staff. Where *Staphylococcus aureus* toxin is indicated by the HACCP plan as a hazard, which has to be controlled in the final product, it is possible to exclude operatives who are carrying *Staphylococcus aureus* on their hands from directly handling the finished product. Such assessment usually includes swabbing an operative's hands after handwashing on three occasions, each occasion being on a different day. If *Staphylococcus aureus* is routinely present on the hands, this person can be excluded from handling the finished product, but is safe to undertake other production activities.

Many personnel hygiene controls can be monitored by direct management observation and recording, e.g.:

- Assessing operative's current health condition – are they fit to work? Operatives are legally required to inform their supervisors that they may be unfit to work and management can then make a decision as to their potential risk to the food product and thus whether they should be sent home/moved to an area of no direct product contact.
- Operative's personal appearance, e.g. hair/fingernails and wearing of jewellery/make-up and correct wearing of freshly laundered, protective clothing.
- Correct handwashing procedure undertaken on operative's entrance to the food processing area and frequency of handwashing after touching areas of contamination, e.g. the face, the floor, waste materials.

An estimate of the transient and resident skin microflora, e.g. after handwashing, count is possible via swabbing or hand contact plates. For more quantitative enumeration, the 'glove juice' sampling procedure has been developed (FDA 1978). A non-powdered sterile glove is donned, the glove is filled with 75 ml of a suitable rinsing solution (e.g. sterile phosphate buffer containing 0.1% Triton X-100) secured at the wrist and the hand is massaged through the glove for 1 min. Aliquots of the sampling fluids are then serially diluted, plated and resultant colonies enumerated (a neutralising agent can be added to the glove juice diluent if bactericidal soaps have been used). This method is used primarily for the testing of hand hygiene products and is not used routinely for quality control (QC) purposes in the food industry.

Non-microbiological verification of handwashing can be undertaken via the use of, for example, video or CCT cameras, where management can subsequently observe video footage of the handwash area. Indirect methods such as monitoring the purchase and use of handwash soaps or paper towels or the use of water meters on the water supply line to the handwashing sinks, can also be used.

### **16.5.1 Protective clothing**

Protective clothing (garments, footwear, aprons, gloves, etc.) can be cleaned and laundered in-house or via outside contractors. The cleaning or laundry process should be chosen to ensure that a decontamination stage is included, via temperature or chemical disinfectants, to reduce any bioburden on the clothing.

The cleaning or laundry process should be established and validated such that an adequate decontamination is ensured. Laundry processes can be microbiologically verified using specialist techniques, e.g. ISO 14698-1.2 (Anon, 2003). The cleaning or laundry process can then be monitored via physical attributes, e.g. temperature, cycle time, disinfectant concentration.

Verification of the cleaning or laundry process is possible using traditional microbiological methods; swabbing for hard surfaces (e.g. footwear) and contact plates for textiles and hard surfaces.

## **16.6 Air and water sampling**

### **16.6.1 Air**

Food products can become contaminated from the air via sedimentation, impaction and direct inclusion. For open food products, transfer of microorganisms from the air is via sedimentation, which has defined rates for particles of given size and buoyancy (Stokes' law, see Lamb, 1994), and the number of microorganisms transferred is dependent on the microbiological loading of the air and the exposure time. When product is transported via air, or when air is blown over a product for cooling or drying purposes, microorganisms can enter the product via impingement in addition to sedimentation, and the number of microorganisms transferred may be related to the volume of air to which the product is exposed. When air is directly added to food products, e.g. for aeration the number of microorganisms transferred may again be related to the volume of air to which the product is exposed.

The primary control of room and transport air is via air filtration and guidance is available as to the level of filtration for particular food processing risk areas and transport purposes. The validation of the performance of air filters usually only occurs for air supplied to high-risk food production areas and is typically validated via air particle counts (filters are classified on their efficacy at removing airborne particles). Monitoring is via pressure differentials across the filters, which is a continuous monitor. It is also possible to occasionally monitor the air immediately exiting air filters via microbiological air samplers but these are often difficult to access. Monitoring air entering a room is more reflective of the condition of the air distribution ducts, which could be useful information in helping to establish ductwork maintenance schedules.

The sedimentation of microorganisms from the air at a particular location and during a specific time period can be verified using settle plates. Settle plates (also known as gravitational or passive air samplers) are typically a 90 mm diameter Petri dish containing a suitable non-selective agar, exposed for a defined exposure time as close as possible to the point at which an indication of the number of microorganisms 'settling' into the product is required. The technique is simple and easy to perform and gives useful results providing that the airflow across the plate, which will determine sedimentation rate, remains constant (e.g. sampling should not be undertaken with doors open which are normally closed). Similarly, samples should not be taken when non-typical processes are in operation around the sampling point which may affect aerosol particle size, e.g. wet cleaning. Sedimentation

techniques do not give an assessment of the number of microorganisms in the air, only those that sediment to the surface and the accuracy of the technique is limited to the number of colonies that may be accurately counted on the surface of the plate, which in turn will be related to the exposure time. Prior trials are required, therefore, to establish such exposure times.

The general level of microorganisms in the air can be verified by capturing airborne microorganisms onto agar, into fluids or into a filter matrix, described as 'active' air sampling. The majority of commercial air samplers that are available for food factory air sampling are of the impaction type. The principle of impaction samplers is that air is drawn onto and over the surface of an agar plate such that the air is forced to quickly change direction to move around the plate. Due to inertia, some particles are unable to follow the air directional change and carry on in their original direction, thus impacting on the agar surface where they are captured. The size of the particles that are captured is dependent on the air velocity over the agar surface; the slower the velocity, the larger the particle size captured (a higher velocity is needed to give smaller particles sufficient inertia to overcome their aerodynamic drag and cause them to impact). The velocity of the air drawn into the sampler is typically controlled by drawing the air through orifices of a known size at a constant velocity. The number of particles captured is thus dependent on the volume of air that is drawn over the surface.

The most common commercial samplers work by drawing air through a perforated (or 'sieve') frontplate onto the surface of a Rodac™ plate or Petri dish. Alternatively, other samplers draw air over the surface of pre-poured agar collection strips. The accuracy of all impact samplers is determined by the volume of air sampled and the sampling flowrate, and the distance between the frontplate and the agar surface. The sampled air volume can be calibrated by measuring the inlet velocity of the air with a suitable calibrated airflow meter and converting this to a sampling volume by calculation from the diameter of the air inlet. Note that some samplers have built-in control systems that can vary the air intake velocity to compensate for low battery life. Whilst these samplers will always sample a set volume of air, they will not have a constant air velocity that will affect the size and number of particles captured. The distance between the air intake and the agar surface should be kept consistent by always using a measured volume of agar when pre-pouring plates or using commercially prepared plates.

As with sedimentation techniques, the accuracy of the methods is determined by the ability to count colonies on the agar surface, which is related to air sample volume and contamination levels. Again, prior trials are required to establish suitable sample volumes which can be pre-set on the samplers or can be varied by manual sampling times, though it is recommended that where possible, a minimum of 100l is sampled.



Single plate impact samplers tend to collect large (>15 micron) particles rather than small (<4 micron) particles and may thus estimate only a small proportion of the total airborne microbial population. As they only enumerate microorganisms on large particles, single plate impact samplers also cannot predict the number of microorganisms settling out of the air into a food product at a given process step. Multistage, cascading samplers such as the Andersen sampler (Atlanta, Georgia, 30336 USA), in which microorganisms are captured onto agar plates in a number of stages, are better able to correlate microbial numbers and particle sizes, the information from which can then be used to predict food contamination by sedimentation. The air is accelerated between each stage so that larger, heavier particles impact on the first stage whilst smaller and smaller particles impact onto subsequent stages. The Andersen sampler is, however, much more difficult to set up for factory air sampling and is not recommended for routine use.

Filtration methods are available in which air is drawn through a suitable holder containing a cellulose, glass fibre or membrane filter. Filters remove microorganisms from the air via a number of mechanisms including direct interception, inertial deposition, diffusion deposition and particle attraction (e.g. electrostatics). After sampling the membrane is either broken up in diluent and serially diluted or incubated directly onto an agar surface to allow a range of airborne concentrations to be sampled. Again, prior trials are required to establish the best enumeration technique. Filtration is best suited to yeasts and moulds as vegetative cells may become dehydrated and die before incubation. More so than the other techniques, the filter holder must be sterile to avoid contamination problems.

Filtration techniques can also be used to sample the microbiological load of compressed air, though the pressure of the compressed air must be reduced by a suitable in-line reducer to prevent damage to the filter and allow a more gentle collection action. Compressed air can also be fed into a large sterile bag or chamber, from which the air can be subsequently sampled at a lower pressure. Alternatively, a measure of the potential microbial contamination of compressed air can be obtained by swabbing the inside of the in-line water traps, i.e. anywhere in the compressed air line that microorganisms could survive/grow, though the compressed air should be switched off prior to sampling.

Very occasionally, purpose-built, stainless steel impingement samplers are used in the food industry. These work on the same principle as cyclonic air filters except that a sampling fluid is introduced around the filter sides to collect microorganisms forced onto the sides via centripetal acceleration. The sampling fluid is then collected and enumerated via standard pour or spread plate techniques.

Both passive and active air sampling should be undertaken using non-selective growth media as microorganisms present in aerosols are physiologically different from those in suspension for which selective



growth media have been developed. To obtain consistency between sampling periods, samples should be taken under 'normal' factory operating conditions. Sampling should take into account when non-typical processes, likely to give rise to high airborne counts (e.g. cleaning operations or the presence of large numbers of people), are in operation around the sampling point. Similarly, sampling should be taken into account if operations are in progress which significantly affect air flows around the point of sampling, e.g. fans, open doorways, particularly to external areas.

It is not possible to easily compare the results from different air sampling methods. This is because all methods sample in a slightly different way (sampling principle, i.e. sedimentation, impaction, impingement or filtration; air velocity; volume and time) which will result both in different sized airborne particles being collected and different sampling pressures being applied to the airborne particles which may affect viability.

In still air conditions it is possible to calculate the rate of product infection via sedimentation from the air using the equation (Curiel *et al.*, 1999):

$$R = v \times c \times a \times t$$

where  $R$  = infection rate

$v$  = settlement rate approximated to  $3 \times 10^{-3} \text{ ms}^{-1}$

$c$  = count of microorganisms per  $\text{m}^3$

$a$  = surface area of the exposed product in  $\text{m}^2$

$t$  = exposure time in seconds.

For example if the opening of a jar is  $3.5 \times 10^{-3} \text{ m}^2$ , the exposure time is 2s and the airborne count  $800 \text{ m}^{-3}$ , the infection rate will be 0.0168 or approximately one microorganism will enter every 60 jars.

### 16.6.2 Process water

Reused water used as a process aid, e.g. for product cooling, washing and transporting (fluming) open products and for cleaning and disinfection may, based on an appropriate risk assessment, require treatment to ensure the same microbiological quality as for potable water used as a product ingredient (Holah, 2012). The performance of such treatment systems will require monitoring, e.g. by chlorine or redox levels and verification for microbiological control. Other environmental water sources that might require sampling for the potential detection of pathogens or indicator organisms could include condensation, leakage water, bootwashers, cleaning soak tanks, recovered water in CIP or traywashing systems and industrial cooling water systems.

Sampling 'environmental' water is usually undertaken using modified surface sampling methods such as swabs, dipslides or sterile pipettes or can be collected into sterile sample bottles. These methods are also useful when sampling slightly larger water volumes, e.g. utensil or cleaning equipment soak tanks.

The concept of the microbiological sampling of larger volumes of process waters is, in effect, identical to sampling potable water sources and is referenced in *The Microbiology of Water 1994, Part 1 – Drinking Water* (Anon, 1994). Two methods are applicable; sampling the water via a sampling tap or outlet into a sampling bottle or sampling the water volume directly using a ‘dip’ sample bottle. Generally, sampling from a purpose-built sampling tap or outlet is preferred as it is difficult to sample water aseptically from bulk volumes and there may be safety hazards to the sampling operative associated with this.

Sample taps should be simple in design, in good repair and facilitate disinfection. At the point of sampling, taps should be clean, free from extraneous matter (e.g. oil, grease, slime, product debris) or cleaning and disinfection chemicals. To ensure that the microorganisms collected in the sample are reflective of the water bulk phase and not the sample tap, it may be appropriate to clean and disinfect the tap before sampling. Disinfection can be via heat or via chemicals, usually sodium hypochlorite solution. The sampling tap or line is then opened and sufficient water allowed to run, to flush the tap or line until a representative water sample can be collected. The time that the tap or line should remain open prior to sample collection is dependent on the design of the sampling tap and its distance from the bulk water phase, which should be as short as possible.

Prior to taking a dip sample and dependent on the size and the access to the water system, thorough health and safety risk assessments should be undertaken to minimise any risks to the sampler. Dip samples have to be undertaken in such a manner that the sampling bottle or the sampler does not contaminate the water sampled. Dip samplers can be prepared by attaching wide mouthed sample bottles to supporting wires or chains, which are then wrapped in autoclave bags and sterilised, with the bottle caps being sterilised separately if required. Alternatively, single-use dip samplers mounted onto short handles can be purchased commercially. Dip samplers should be used in such a way that a representative sample of the water system assessed is obtained. This may require submerging the sample bottle to a relevant depth but no sediments or biofilms should be disturbed during sampling.

The volume of the sample taken will be related to the likely contamination of the water (e.g. potable waters may be  $<100$  colony forming units (cfu)/ml whereas non-food contact cooling tower waters may be  $>10^4$  cfu/ml) and the method of assessment (e.g. direct plating out of the water sample or the prior concentration of the microorganisms by filtration). Sample bottles should be made from autoclaveable plastic, to allow for reuse, or should be pre-sterilised disposables. Glass bottles must not be used within factory environments. As most water samples to be examined are likely to contain chlorine, sodium thiosulphate should be added to the sampling bottles prior to sterilisation to neutralise the chlorine. A concentration of 18 mg/l should neutralise up to 5 mg/l of free and combined residual chlorine (PHLS, 1953),

which equates to 0.1 ml of a 1.8% m/V solution of sodium thiosulphate per 100 ml of bottle capacity. If higher levels of chlorine may be present, sodium thiosulphate levels should be increased accordingly.

After collection, samples should be transported and stored at chill temperatures (2–10°C) and should be processed within 6 hours as evidence suggests that there is a significant reduction in faecal colony counts after 24 hours storage as compared with 6 hours (Anon, 1994).

## **16.7 Practical sampling**

Health and safety training for operatives undertaking sampling work is essential, as they may put themselves at risk. In many cases, they need to sample difficult-to-reach areas that are difficult to clean or dead areas in which microorganisms may be harboured. An understanding, therefore, of the dangers of moving machine parts, interlocked guarding, the need to switch off machinery at the machine and at the mains supply, and the need for adequate supports (ladders and platforms) when sampling off the ground, etc., is essential, particularly if the sampling operative is asked to sample areas and equipment at sites in which they are not familiar.

### **16.7.1 Sampling equipment**

Sampling equipment and utensils should be clean, sterile (as appropriate), well maintained, and appropriate for food factory use. Sampling systems that contain potentially hazardous materials, e.g. glass (or hard and/or brittle plastics) must not be used in food factories. In addition, sampling systems that create a hazard during their use, for example swabs, should be designed to minimise fracturing or splintering, e.g. plastic or metal swab sticks, should be used. Sampling equipment should be made of stainless steel or other suitable materials that are easy to clean and disinfect and are resistant to corrosion. In addition, they should be easy to dismantle to facilitate cleaning and disinfection of internal parts. Equipment requiring to be connected to a mains supply for power should be avoided, though if this is not possible the plug should be suitably sealed (ideally to IP56). For battery powered samplers, recharging of sampling equipment should be undertaken in the laboratory, not in food processing areas.

Sampling equipment should be well maintained, serviced to their manufacturers appointed schedules and routinely calibrated. Equipment must be decontaminated (sterilised or disinfected as appropriate) before entering food production areas (particularly if stored in the microbiology lab), between samples as appropriate, before entering high-risk food processing areas (if it has previously been used in low risk) and between sites. Wherever stated, equipment or media manufacturer's instructions on

the use of their products should be carefully followed to maintain sampling integrity.

### 16.7.2 Sample taking

Care should be taken to ensure that microbiological sampling is undertaken as aseptically as possible. This includes the:

- correct handling of the sampling devices (commercial or made up in the laboratory) to ensure that they are not opened or damaged during transport to the sampling site;
- correct sampling of the target site so that no other surface is touched; and
- correct handling of the completed samples to ensure that they are not damaged or contaminated prior to arrival in the laboratory.

Similarly, care should be exercised during the sampling period such that the operative taking the sample should not personally contaminate the sample. For instance during swabbing, if the sampling operative touched the surface to be sampled or the part of the swab stick that enters the resuspension fluid, the result would be spurious. Similarly, operatives sampling the air with hand-held air samplers may actually be sampling themselves rather than the factory air if the sampler is held too close to them or downwind of them.

The sample container should be fully labelled as appropriate. This may include:

- a reference number or code;
- the date and time of sampling;
- the sampling site;
- the sampler's name or initials.

During the sampling period it is important to note what is happening that might affect the result of the sample analysis. For example, if cleaning operations are being undertaken in the surrounding area, the release of cleaning aerosols, potentially containing large quantities of microorganisms, can affect the results of air sampling, settle plate and large surface area swabbing techniques. Similarly, line downtime, line maintenance, the fitting of new air filters, whether specific equipment is in operation (e.g. bandsaws), the number of operatives on the line and the type of product being processed, etc., can all impinge on the level of contaminants captured during the sample period.

Finally, care must be exercised to ensure that no part of the sampling system can contaminate the food product. This can occur directly, e.g. wood from a broken swab stick or plastic from a broken sample bottle, or indirectly, e.g. a sampling fluid or gel residue left on the surface may encourage the subsequent growth of surface adhered microorganisms. Such

residues need to be removed by, for example, using an alcohol/disinfectant-impregnated wipe. Because residues may be left on surfaces, the use of specific media within the sampling method that encourages the selective growth of specific pathogens should be avoided if possible. It is also good practice for sampling operatives to always count the number of sampling devices they have before entering food processing areas, and on leaving them, to make sure that all devices (and any parts thereof, e.g. broken swab ends) are accounted for.

Controls should be undertaken, wherever possible, throughout the whole of the sample preparation, sampling, transport and analysis stages. In particular, sterility checks for media and sampling equipment such as swabs should be undertaken to indicate that samples have not been cross-contaminated.

### **16.7.3 Sampling fluids**

Other than rapid hygiene tests (ATP, protein analysis) which are analysed immediately, samples require transporting to a testing laboratory. Microbial samples have to be handled in such a way that changes in the microbial composition and viability are minimised between the time of sampling and the time of analysis. This is accomplished by using suitable sampling fluids that minimise stress, whilst at the same time, neutralising the effect of any disinfectant residues captured during sampling.

Sampling fluids (diluent) are primarily designed to maintain microorganisms under isotonic conditions and to reduce physiological stress during the period prior to analysis. For the majority of microbial sampling situations, a diluent based on that as recommended in BS 6887-1: Part 1 (Anon, 1999) should be used. The diluent is based on a solution of peptone (1.0 g/l) and sodium chloride (8.5 g/l) adjusted to obtain pH 7.0  $\pm$  0.2 after sterilisation. A suitable surfactant (e.g. polysorbate 80) is sometimes added as this may enhance microbial removal from surfaces. For the sampling of specific pathogens it is also possible to use the appropriate pre-enrichment fluid. Consideration should be given, however, to the duration of the transport and storage phase and what impact this may have on the multiplication of other microorganisms within the sample.

### **16.7.4 Disinfectant residue neutralisation**

If the sampled surface is likely to contain disinfectant residues, a neutralising solution must be added to the diluent. In essence, this is because microorganisms attached to a surface are much more resistant to disinfectants than when in suspension (Holah, 1995). When microorganisms are removed from surfaces by swabbing and taken into the swab matrix, their microenvironment is changed from adherence to suspension. If disinfectant residues have not been neutralised they could quickly die and thus present

an unrepresentative picture of the surface microbial population at the time of swabbing.

The critical parameters in neutralisation are the choice of neutraliser and its concentration relative to the amount of disinfectant likely to be present in the sample to be neutralised. A universal neutraliser, as currently recommended for all food industry disinfectants (Anon, 2009), is as follows:

Lecithin	3 g/l
Polysorbate 80	30 g/l (V/V)
Sodium thiosulphate	5 g/l
L-Histidine	1 g/l
Saponin	30 g/l

made up in 0.25 mol/l phosphate buffer ( $\text{KH}_2\text{PO}_4$ -NaOH adjusted to pH 7.2) or other sampling fluids.

This neutraliser is formulated to neutralise in the ratio one part in-use disinfectant concentration to nine parts neutraliser. As the quantity of disinfectant present in the sample is likely to be very low, a mixture of 1 ml of the universal neutraliser to 9 ml of the sampling fluid is acceptable for the majority of occasions.

## 16.8 Sample transport and processing

### 16.8.1 Transport

To minimise the opportunity for either growth or death of the microorganisms within the sample, samples should be processed as soon as possible after the time of sampling. In most cases, however, this is either impractical (e.g. post-cleaning samples are taken at 5.00 am whilst the laboratory staff start work at 8.00 am) or impossible (e.g. the samples have to be transported to a central laboratory or contract laboratory to be processed). Whilst it is often stated that the maximum permissible time between sampling and processing is usually regarded as 24 hours, what is more important is consistency of time and temperature between sampling and processing such that repeat routine samples from the same sampling site, or for the same purpose, are held under consistent conditions such that variations between samples are minimised. In all cases the time of sampling and processing should be recorded and if there is a significant time difference from that of normal procedures this should be noted with the sample results.

Samples from which a TVC is to be obtained, should be transported and stored under chilled conditions to prevent microbial growth. Temperatures should ideally be as low as possible (ideally 2–5 °C) but not frozen, and as with time, constancy between the handling of repeat, routine samples is more important than actual temperatures. In all cases the temperature of

the sample on arrival of the laboratory should be recorded and if there is a significant temperature difference from that of normal procedures this should be noted with the sample results.

Samples to be examined for the presence of pathogens should be kept at temperatures that would maximise their resuscitation and minimise their loss of viability. If transport times are excessive, however, it is possible that the background flora could grow to such an extent that the presence of the pathogen could be masked. It may be necessary, therefore, to chill such samples. Dry swabs or samples of dry product, should be transported and stored at ambient temperature and may need to undertake a resuscitation stage prior to enumeration.

Samples should be transported to the laboratory in suitable containers. In most cases, this will involve the use of an insulated 'coolbox', which is kept cool by adding a suitable number of frozen eutectic 'ice packs' or other cooling media to the container. Insulated coolboxes do not cool sampling media, they only help maintain its temperature on entrance to the coolbox. If low-temperature storage and transport of samples is required, sampling fluids must be pre-cooled, stored in the coolbox until use, used quickly during sampling and then returned immediately to the coolbox. The coolbox should then be able to maintain the samples chilled for substantial time periods, e.g. 24–30 hours. Alternatively small, portable, chilled incubators are available which can run on either mains AC voltage or a 12 volt DC power supply. These incubators will chill and maintain samples to a set temperature, which can be verified by a range of temperature recording and data logging devices. Coolboxes and chilled incubators should periodically be cleaned and disinfected as necessary.

### **16.8.2 Sample receipt and handling**

Samples arriving at the laboratory should be checked for condition, labelling and temperature as appropriate, within a suitable sample receipt system. The time and temperature at arrival should be noted and it may be appropriate to assign each sample with a unique identifier. Traceability of samples should be retained by recording the place and conditions of storage within the laboratory throughout the time of sample processing. On receipt at the testing laboratory, samples should be stored between 2–5 °C until the time of processing (Anon, 1996). Samples that have been stored at very low temperatures should be allowed to acclimatise towards ambient temperature before being processed to reduce temperature stresses.

Following sample processing, samples should be retained for a suitable time period, commensurate with the analysis undertaken. With the further development of molecular techniques, particularly related to genetic fingerprinting, food manufacturers, particularly of RTE products, are beginning to consider the retention and storage of any pathogens identified. This can aid in potential troubleshooting studies and may provide useful



information to allow a better understanding of factory ecology and the persistence of particular strains. As a general rule, pathogens should not be stored in laboratories undertaking routine identification and enumeration tests as the potential and impacts of any cross-contamination is considerably. Storage at another (central) facility is preferred.

### **16.8.3 Sampling validation**

As with all scientific methods, the acceptability of the results from sampling studies is questionable if the methods have not been appropriately validated. The collection of microorganisms or other hygiene markers from the processing environment by sampling is virtually impossible to validate if the original starting conditions are unknown. It is possible, however, to validate aspects of the sampling procedure (Holah and Hall, 2004).

Initially, the ability of the chosen sampling method to capture the target microorganism from the target surface can be validated. A known number of the target organism is added to a range of target environmental surface(s) to be sampled (e.g. stainless steel, floor finishes, conveyor belting). The size of the inoculum should be in proportion to the typical level of target microorganism that could be found. Following inoculation, the surface is sampled in the normal way and the sample is enumerated directly. The number of microorganisms recovered from the surface can then be compared with the number inoculated.

The validation has two components: the recovery of the target microorganism from the test surface and the recovery of the target microorganism from the sampling matrix. It is possible to assess these recoveries jointly, as described above, or the second element, the recovery from the sampling matrix, e.g. a swab or sponge, can be tested separately. In this case, a known inoculum of the target microorganism can be added directly to the sampling matrix after which the sampling matrix is directly enumerated. The number of microorganisms recovered from the swab matrix can then be compared with the number inoculated.

There are no established guidelines with regard to the expected recovery of microorganisms from surfaces using traditional surface sampling techniques. The verification basically works on two levels: primarily, are target organisms recovered per se, i.e. does the sampling method inherently work (for the target microorganism and surface chosen)? Secondly, what is the recovery efficiency? The former must be proven; the latter gives an idea of the overall degree of error within the method and will be dependent on the inoculum level.

If pathogens are used as test organisms, the evaluation has to be undertaken in the laboratory and pieces of the relevant surfaces have to be appropriately acquired. Under no circumstances should the validation of hand sampling be undertaken by adding target microorganisms to human skin. The ability of commercial swabbing and/or contact plates to recover



microorganisms from a range of surfaces may have been undertaken by the media manufacturers. Details should be available on request.

The capability of the sampling/transport medium to maintain the viability of selected microorganisms (e.g. the pathogen usually analysed for), from the point of sampling to the time of sample enumeration, can then be validated. To the medium, containing any neutraliser and surfactant, is added a known quantity of the selected target microorganism(s), a portion of which is also enumerated at the same time. At a later time and at a given temperature, representing the typical transport and storage conditions, a second sample is then taken and enumerated. If the count of the sample after the simulated transport and storage period (surviving cells) is >50% of the test microorganism (inoculum), the medium's ability to maintain the test microorganisms viability has been demonstrated.

The selection of the target microorganism(s) inoculum level is important. If the selected microorganism is a pathogen, it would be very unlikely that the organism would be found in significant quantities within the processing environment. As a compromise between examining the survival of potentially single cells and the presence of sufficient cells to verify survival an inoculum of 100–1000 cells would thus be an appropriate challenge. If the selected microorganism(s) was more general, e.g. Enterobacteriaceae or TVC, a challenge of 1000 to 10000 may be more appropriate. The ability of commercial swab transport media to support the growth of a range of captured microorganisms may have been undertaken by the media manufacturers. Details should be available on request.

As part of the transport validation, the variation in transport temperature should be evaluated by assessing coolbox or chilled incubator variables. These include the volume of the sample, the starting temperature of the sample, different container loads (e.g. full or half full) and the number of gel packs used.

Finally, and if sampling is undertaken from surfaces to which disinfectants may be applied, the capability of the selected neutraliser to neutralise the effects of any disinfectant residues present on the sampled surface may be validated. Full details are given in Anon (2009) but, in principle, the volume of sampling fluid drawn up from a surface by the sampling technique is first estimated. This volume of disinfectant, at twice the manufacturer's recommended concentration (worst case scenario) is added to the transport medium containing the neutralisation fluid, equilibrated to the sampling temperature. The sampling/transport mixture, containing the disinfectant, is left for 5 min for the solution to fully mix and the neutraliser to react with the disinfectant. An appropriate inoculum of the selected target microorganism(s) is prepared and enumerated. A volume of inoculum (the same as the disinfectant) is added to the sampling fluid/disinfectant mixture and left for 5 min. After this time, surviving cells are enumerated. The neutralisation potential of the sampling/transport medium is verified if the surviving cell count is not <50% of the inoculum count.

The validation should be repeated for every class of disinfectant used in the food processing area (e.g. quaternary ammonium compounds or chlorine-based biocides) and for every target microorganism. This is because the ability of a neutralising agent to neutralise the disinfection properties of the disinfectant is dependent on the type of disinfectant used and the target microorganism of concern.

## 16.9 Conclusion

Whilst microbiological sampling of the processing environment has been undertaken for many years and sampling techniques are generally well established, the concept of the prerequisite management plan and the processing environment plan as illustrated in Chapter 2 and this chapter were first mooted in 2011. As such, they are both new and developing and food factory technical and laboratory management are encouraged to try them and provide feedback as to their usefulness. Advances have also been made in the practical management of sampling, primarily driven by factory and laboratory auditing schemes, which are helping to ensure that the microbial flora assessed at the time of sample processing is as close as possible to the flora at the point of sampling. Future advances are likely to focus on the detection of DNA on surfaces, with implications both for selective microbial detection but also for allergens and cross-species contamination (e.g. pork in beef in meat-cutting plants).

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## Economics and management of hygiene in food plants

**H. Timmerman, Sealed Air Corporation, USA and  
European Hygienic Engineering and Design Group, Belgium**

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**Abstract:** The lack of proper cleaning and disinfection procedures can cost plant operators a lot of money. The cost is directly related to several known parameters, such as water, labour, energy and chemicals. There are, however, many indirect and even hidden costs which can influence the cost and the economics of cleaning. There are many ways, without compromising food safety, that companies in the industry can make their cleaning processes more efficient, more cost effective and less damaging to the environment. The real cost of cleaning is a crucial part in the determination of the cost of non-quality, as part of the total cost of quality. To make sustainable improvements, efficient cleaning, with its associated reductions in cleaning costs, needs to be part of the culture of the organisation.

**Key words:** cleaning, food hygiene, economy, labour, energy, chemicals.

### 17.1 Introduction: the perception of cleaning costs as an example of the perception of hygiene

Management in the food industry often associates ‘hygiene’ with ‘cleaning’ and, as with other materials purchased for food production, seeks to reduce cleaning costs, usually by reducing cleaning chemical use and/or purchase price. This chapter aims to demonstrate that ‘hygiene’ has a wide impact within food manufacturing and performance cannot always be measured in monetary terms.

The lack of proper cleaning and disinfection procedures can cost plant operators a lot of money. If this leads to a food safety incident with a recall procedure, it has been calculated that the day after a recall announcement, the stock price of the affected company underperforms the sector index by an average of 2.3%. A company with a poor recall execution process could show a decline of up to 22% within 2 weeks of the recall announcement

(Deloitte Consulting, 2011). In cases without recall, often this loss is not so obvious to management. It shows up in terms of customers going elsewhere, poor employee morale (this is sometimes blamed on inferior personnel), unreported spoilage problems or poor food quality in retail or restaurants (resulting in a lack of repeat business). More obvious to management are direct complaints and government intervention ranging from retail audits or government food safety bodies. Lack of proper cleaning and disinfection can cause increased returns of products, shorter shelf-life resulting in high amounts of food waste, less profit and can invite the threat of possible operation shutdown. Good cleaning and disinfection does not cost, it pays. Cleaning is vital to ensure food safety and is a prerequisite in a mandatory hazard analysis and critical control point (HACCP) system within any food business operation. There are many ways, without compromising food safety, that companies in the industry can make their cleaning processes more efficient, more cost effective and less damaging to the environment. The real cost of cleaning is a crucial part in the determination of the cost of non-quality, as part of the total cost of quality.

## 17.2 The real cost of hygiene

Measuring the cost of cleaning in order to obtain a realistic understanding of the cost components is quite complex, as several direct and indirect cost factors play a role (Antle, 1999). The direct factors are easily understood and in a modern food facility can be obtained from the management information system. The indirect factors, not directly related to physical measurements, require a holistic view of costs, as a consequence of an integrated quality approach. Performance measurement is a fundamental building block of total quality management (TQM) and a total quality organisation. Historically, organisations have always measured performance in some way through the financial performance, be this success by profit or failure through liquidation. However, traditional performance measures, based on cost accounting information, provide little to support organisations on their quality journey, because they do not map process performance and improvements as seen by the customer. In a successful total quality organisation, performance will be measured by the improvements seen by the customer as well as by the results delivered to other stakeholders, such as the shareholders. Reviewing the performance of an organisation is also an important step when formulating the direction of the strategic activities. It is important to know where the strengths and weaknesses of the organisation lie, and as part of the '*Plan – Do – Check – Act*' cycle, measurement plays a key role in quality and productivity improvement activities.

The cost of doing a quality job, conducting quality improvements and achieving goals must be carefully managed, so that the long-term effect of

quality on the organisation is a desirable one. These costs must be a true measure of the quality effort, and are best determined from an analysis of the costs of quality. Such an analysis provides a method of assessing the effectiveness of the management of quality and a means of determining problem areas, opportunities, savings and action priorities. Quality-related activities that will incur costs may be split into prevention costs, appraisal costs and failure costs.

Prevention costs are associated with the design, implementation and maintenance of the TQM system. They are planned and incurred before actual operation, and could include:

- product or service requirements – setting specifications for incoming materials, processes, finished products/services;
- quality planning – creation of plans for quality, reliability, operational, production, inspection;
- quality assurance – creation and maintenance of the quality system and also training – development, preparation and maintenance of programmes.

Appraisal costs are associated with the suppliers' and customers' evaluation of purchased materials, processes, products and services to ensure they conform to specifications. They could include:

- verification – checking of incoming material, process set-up, products against agreed specifications;
- quality audits – check that the quality system is functioning correctly;
- vendor rating – assessment and approval of suppliers, for products and services.

Failure costs can be split into those resulting from internal and external failure. Internal failure costs occur when the results of work fail to reach designed quality standards and are detected before they are transferred to the customer. They could include:

- waste – doing unnecessary work or holding stocks as a result of errors, poor organisation or communication;
- scrap – defective product or material that cannot be repaired, used or sold;
- rework or rectification – the correction of defective material or errors;
- failure analysis – activity required to establish the causes of internal product or service failure.

External failure costs occur when the products or services fail to reach design quality standards, but are not detected until after transfer to the customer. They could include:

- repairs and servicing – of returned products or those in the field;
- warranty claims – failed product that are replaced or services re-performed under a guarantee;

- complaints – all work and costs associated with handling and servicing customers' complaints;
- returns – handling and investigation of rejected or recalled products, including transport costs.

Many organisations will have true quality-related costs as high as 15% of their sales revenue, and effective quality improvement programmes can reduce this substantially, thus making a direct contribution to profits (DTI, 2007). A way of calculating quality costs is the process cost model, which categorises the cost of quality (COQ) into the cost of conformance (COC) and the cost of non-conformance (CONC), where:

$$\text{COQ} = \text{COC} + \text{CONC}$$

where COC is the process cost of providing products/services to the required standards, by a given specified process in the most effective manner and CONC is the failure cost associated with a process not being operated to the requirements, or the cost due to the variability of the process.

To identify, understand and reap the cost benefits of quality improvement activities the following fundamental steps should be included in the approach:

- Management commitment to finding the true costs of quality.
- A quality costing system to identify, report and analyse quality-related cost.
- A quality-related cost management team responsible for direction and coordination of the quality costing system.
- The inclusion of quality costing training to enable everyone to understand the financial implications of quality improvement.
- The presentation of significant costs of quality to all personnel to promote the approach.
- Introduction of schemes to achieve maximum participation of all employees.

The system, once established, should become dynamic and have a positive impact on the achievement of the organisation's mission, goals and objectives.

### 17.3 Direct factors

The most direct impact on the plant's hygiene will come from cleaning and disinfection practices. There are a significant part of many food and drink manufacturers' costs, and one that is increasing each year at a rate above inflation. A major reason for this is the rising cost of water supply and effluent discharge. Between 2001 and 2007 the average mains water cost for an industrial user rose by 40% and the average trade effluent discharge cost rose by 56%, and this trend is likely to continue.

The sum of the individual items used in a cleaning and disinfection programme represents the total cost. Cleaning costs vary significantly from site to site. As a rough guide the typical breakdown of cleaning costs, excluding labour costs and lost product costs, would be:

- water/effluent 44%;
- energy 30%;
- chemicals 26%.

The cost of cleaning is influenced by many factors. The distribution of the costs will vary by type of facility and method of cleaning. The factors which will have a direct impact are numerous, and will each have a major or minor impact on the total balance. An overview will include: cleaning supplies, safety equipment, water, labour, energy, detergents or chemicals, type and frequency of cleaning, overhead expenses, lost production time costs. Each element will have an individual breakdown.

### **17.3.1 Cleaning supplies**

Cleaning supplies are all the physical needs to obtain a good cleaning result. They consist of purchased goods, which are often depending on general maintenance budgets or non-productive items (NPI). An overview will include buckets, brushes, scrub pads (green pads), hoses and nozzle assemblies, squeegees, shovels, brooms, mops, disposable cloths, paper, vacuum cleaners and other items.

### **17.3.2 Safety supplies**

Safety supplies are often legal requirements within a safety, health, and environmental policy (SHE), but are related to cleaning chemicals which are most of the time handled as hazardous chemicals. These supplies include gloves, boots, waterproof suits, eye protection, face shields, helmets, respirators and confined space equipment.

### **17.3.3 Water**

Most cleaning in the food environment is performed wet. Water will have a huge impact on the total cost, the breakdown of which will have several elements, such as the purchase price from the municipality. If water is used from owned wells, there will be pumping costs and treatment costs for purification and softening. Intermediate storage tanks and distribution systems will require a periodical hygiene maintenance programme, in order to guarantee potable process water at all times.

The waste stream expenses add to the total water cost due to the cost of discharging the water to a sewer or surface water environment. This cost can be more than the cost of purchase, as countries or regions will calculate



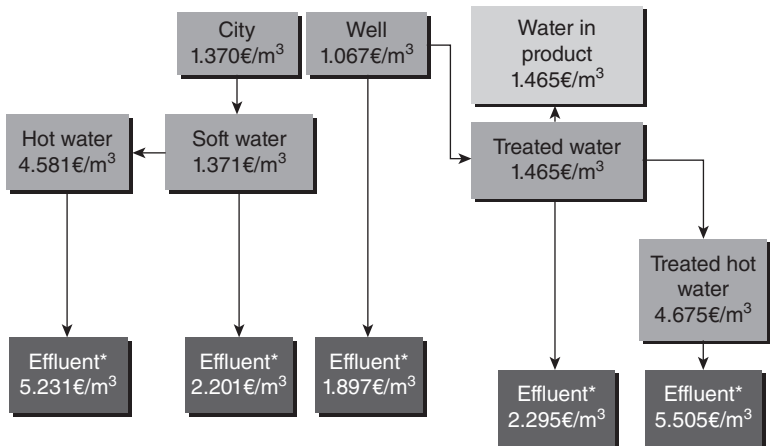
a pollution fee based on volume and the pollution load, such as chemical oxygen demand (COD), biological oxygen demand (BOD), suspended solids, phosphate and nitrate surcharges.

There is a strong relationship between water use costs and effluent discharge costs. The scope for savings in effluent discharge costs is likely to be even greater than for water supply cost savings, highlighting the overall cost benefits to be gained from more efficient water management and the reduction of water use.

Cleaning accounts for as much as 70% of a site's total water and effluent costs in some food and drink sectors, and a significant percentage in most, as shown in Table 17.1. If waste water has to be treated, the operational cost of a waste treatment facility will add significantly to the total water cost. Costs may comprise operating costs (usually per m<sup>3</sup>) and depreciation of treatment plant. Other costs that may be incurred include off-site waste treatment and disposal charges. Treatment and cleaning chemicals are lost via the effluent. Such chemicals can be valuable, in addition to increasing effluent costs due to contamination. In Fig. 17.1, a typical breakdown is shown of water costs in a beverage plant.

**Table 17.1** Typical examples of cleaning water use as a percentage of total water use

Type of site	Cleaning water use (%)
Bakery	70
Soft drinks manufacturer	48
Brewery	45
Jam manufacturer	22



**Fig. 17.1** Water cost breakdown, Aquacheck in a beverage plant by Diversey. \*Sum of incoming and effluent cost. Effluent cost is 0.83 €/m<sup>3</sup>.

### 17.3.4 Labour

The cost of labour required for cleaning is the most variable of all costs, as this varies hugely depending on the cleaning method, the disposition of the correct tools, the training level, the level of automation and the local remuneration policy. In the food industry many cleans are executed during night times or weekends, which will require overtime expenditures. People performing the cleaning tasks can vary from skilled and trained food operators, to poorly qualified temporary workers or even students.

In calculating the labour cost, management expenses should also be integrated. In some cases cleaning is accountable to a dedicated hygiene department or is partially or completely outsourced to contact cleaners. Avoiding or speeding up the cleaning operation can result in substantial labour cost savings and reduced plant downtime.

### 17.3.5 Energy

In cleaning and disinfection there are several parameters which contribute directly to the energy cost. The factor 'heat' used as hot water is generated from direct or indirect heating, most of the time by the use of steam.

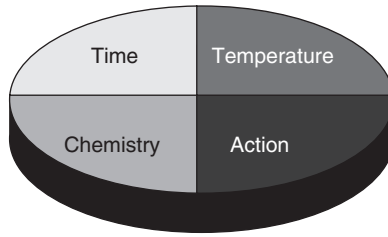
Heat can be required to maintain a cleaning-in-place (CIP) installation in a standby mode, where solutions are kept at a constant temperature to ensure a correct cleaning temperature for all moments that cleaning is required. Steam consumption can be measured and converted directly to an accountable cost. For every 10 °C increase in water temperature there is an additional cost of typically 0.08 €/m<sup>3</sup>, if water is heated by gas, oil, steam, etc. or up to 0.5 €/m<sup>3</sup>, if water is heated by electricity.

Within air handling units, increasing fan speed together with increasing air temperature can be used to aid process area drying and or prevent the formation of condensation following wet cleaning operations. In several cleaning steps, cooling might be required to lower the surface temperatures to a temperature suitable for production. This will require also an inverse heat transfer, and will also have an energy impact.

Another relevant costs is electricity, as the driving power for motors, which are present in the process and are running during cleaning. There can be water pumps to boost water pressure for open plant cleaning (OPC), CIP pressure and return pumps, agitators, belt drives, vacuum pumps and air compressors. Electricity use is a function of flow rate, distribution pressure and pumping efficiency.

### 17.3.6 Chemicals

The detergent, often a caustic or acid-based blended chemical, has a direct impact on the cost. However the choice of chemical is primarily dependent on the method of application. Different cleaning methods require a specific use concentration and dosing control, and will have a specific consumption



**Fig. 17.2** Four parameters which have a direct influence on the cost of cleaning.

pattern. Common cleaning methods in the food processing area are external cleaning or OPC by foams or gels, manual cleaning-out-of-place (COP) with foaming of non-foaming detergents, CIP with defoaming or non-foaming chemicals, soaking applications with low mechanical impact such as fryer boil out (FBO) programmes, pressure wash systems with high-pressure installations, and machine operated spray wash installation such as crate washers or cabinet washers.

The Sinner circle (Tamime, 2008) of cleaning indicates, independent of any specific cleaning method and installation, four parameters which have a direct influence on the cost of cleaning (see Fig. 17.2): cleaning time (T), fluid mechanics (A), Detergent or chemistry (C) and temperature (T), also known as TACT.

The selection of the chemical is not just application-dependent: the soils to be cleaned are the primary selection criterion. Also the food contact surface material is a factor in determining the suitable chemicals. Stainless steel will be more corrosion resistant and cleanable than softer metals like aluminium, which will require formulations with a corrosion inhibitor, making the cost of the chemical higher by the composition of more expensive raw materials. The variation of different ingredients can be the cause of different costs for less or more effective cleaning chemicals.

The cost of chemicals can be evaluated from different points of view. Individual cleaning chemicals can be difficult to compare, taking into account all the above-mentioned criteria required for the selection of an effective solution. Also, pricing of the chemicals is highly dependent on the economical volatility of the raw materials that are components of the detergents. Raw materials are usually petroleum-based, which is known to have a very variable pricing level.

Suppliers of cleaning chemicals will offer to their users different pricing mechanisms to overcome these challenges and be able to calculate more correctly the cost factor of the chemicals. The following options are perceived in the market:

- the price per volume purchased in dollars per gallon or/euros per litre, where specific gravity of the product can differ strongly;

- the cost in use where the cost is reflected by the price per volume divided by its dilution rate.

Sometimes costs are bundled and include all costs associated with the cleaning operation and also included, e.g. dispensing equipment.

## 17.4 Indirect factors

Indirect costs are often not directly related to the operational part of cleaning, but can have a major impact on the total cost. They not only include general overhead costs, but also the reduction in production capacity or the output of the factory.

### 17.4.1 Overhead

All upper management and support functions are part of the total cost: human resources (HR) in the selection and training programmes, health and safety officers will have to contribute a major part of their resources as cleaning involves handling of dangerous chemicals and can be the cause of safety incidents, quality control and assurance will have a responsibility in assessing the result by monitoring, verification and validation of new lines. Maintenance operations to plant and building fabric will have a strong influence, including the disassembly and reassembly of equipment pre- and post-cleaning, servicing the dedicated cleaning equipment, and the repairing of unexpected damage due to cleaning.

Building and production equipment wear and depreciation are not calculated in the hygiene economics, but can be influenced by the effect of cleaning and the long-term use of chemicals for cleaning.

### 17.4.2 Lost production time

Another indirect factor which is not easily quantified is the loss of production time due to cleaning and disinfection-related line stops. Many food operations have a scheduled cleaning window, e.g. at night-time, where the total production is at a stop and only cleaning operations are executed. The time and resources required for cleaning are controllable, and the total shutdown is included in the schedule.

In other operations, e.g. in dairy or beverage plants, cleans are undertaken whenever a holding tank is empty or a pasteuriser has exceeded its running time. Some equipment has a direct impact on the plant's production capacity, like the ultra-heat treatment (UHT) plant or the filling lines. In these cases the length of cleaning time is crucial and failures to start on time due to unexpected holds, or alarms, will result in a lower plant efficiency, and hence have a major negative cost impact.

## 17.5 Overview of optimisation tools

The first and crucial step is calculating and knowing existing cleaning costs which will allow for the selection of the best method and practices by management based on desired goals. In cleaning most things can be measured, counted and valued. However, collecting all that information is not easy and is sometimes of little value. The total relevant cost will depend on what cost factors are measured and each cost factor has a relative value within the total.

Companies have the power to control their costs by reducing the amount of water they use, and effluent they discharge. There are many simple no-cost and low-cost measures that can be adopted by companies, whatever their size, to use less water to clean just as effectively.

Cleaning costs are a significant part of food and drink manufacturers' costs and include factors often overlooked. As well as the cost of water, effluent and chemicals, there are lost raw materials/product, energy, labour and plant downtime, which all add to the true cost of cleaning. Many companies are not aware of the overall cleaning costs and assessing these is an important first step to controlling them.

Improving the efficiency and effectiveness of cleaning operations can reduce the time required for cleaning, thereby avoiding production bottlenecks. Companies cut cleaning costs by providing information on methods of cleaning which have the potential to reduce costs without compromising hygiene standards. As with all such guidance, it remains the responsibility of companies to take action to ensure that hygiene standards are being met in each individual case.

A top priority for any company wishing to reduce its cleaning costs is to identify the real overall cost. Often the cost is unknown and is regarded – mistakenly – as being too low to be of concern. The true cost of cleaning may be more than three times the total amount charged for water supply and disposal – and often much more if staff time or production downtime are included. Some of these issues are discussed in this chapter, to help start thinking of the real cost of cleaning to a company.

First, to reduce cleaning costs, a company needs to be in control. A company cannot manage something that is not being measured. Measuring to manage is all about getting and keeping control over the use of water, chemicals, energy, etc., by measuring them and then comparing the use with a target value. This need not be complex, and some of the easiest methods of measurement are described below.

The actual water consumption can be assessed easily using a permanent or portable meter, a bucket and stopwatch (where the time taken to fill a known volume is measured), by estimation or by calculation. The expected consumption can often be obtained from the equipment manufacturer or can be calculated based on a knowledge of how the process is designed to work.

**Table 17.2** Estimated potential for water savings through use of good practice

Application	Current cleaning method	Potential saving if good practice employed (%)
Floor washing	Mains hoses	60–85
	Pressure washing	20–40
Wall washing	Mains hoses	60–85
	Pressure washing	20–40
Pipe cleaning	Pressure washing	20–40
	CIP – total loss system	50–65
	CIP – chemical solution only recycled	40–55
	CIP – final rinse only recycled	40–55
	CIP – chemical solution and final rinse recycled	20–35
Vessel/tanker cleaning	Mains hoses	60–85
	Pressure washing	20–40
	CIP – total loss system	50–65
	CIP – chemical solution only recycled	40–55
	CIP – final rinse only recycled	40–55
Container washing	CIP – chemical solution and final rinse recycled	20–35
	Mains hoses	70–98
	Pressure washing	80–95
Equipment washing	Automatic washer	20–30
	Manual/mains hoses	40–60
	Pressure washing	20–40
Bottle washing	Bottle washer	30–50
Conveyor washing	Mains hoses	60–85
	Pressure washing	20–40

In a measuring to manage system, the usage is monitored and the actual consumption is compared with a target consumption. The target is normally a constant good practice figure (for a regular cleaning process) or a fluctuating figure based on a measure of the cleaning need during the consumption period, e.g. number of items washed or number of product changes. Often the biggest savings can be made through the easiest actions (Table 17.2). There are many opportunities through no- and low-cost good housekeeping measures to improve the efficiency of cleaning operations.

Where good housekeeping practices are implemented it is important to monitor the results to ensure that they are being maintained. A total economic balance will include how much a company pays for water, both annually and per m<sup>3</sup>, and for effluent disposal, both annually and per m<sup>3</sup>.

Each site should evaluate how much of the site's water consumption is used for cleaning purposes. The identification of the major users of water for cleaning purposes is a critical part of the process. Water meters, fixed or portable for any major users, e.g. CIP sets, bottle washers, container washers and wash down ring mains, can be installed to monitor consumptions.

The optimisation process should include the implementation of low- and no-cost opportunities for reducing cleaning costs, after ensuring that hygiene standards will not be adversely affected. The basic principle is that in cleaning, every drop counts. Implementation of dry clean-up methods where possible will have a positive effect on cost and the hygienic result.

The regular consideration of using innovative alternative cleaning methods can have a significant contribution in the total cleaning budget. Many suppliers offer consultancy programmes which can assist with the monitoring, the calculation and the optimisation of the total cost of cleaning.

## 17.6 Conclusion and future trends

Good management of cleaning operations is important to ensure that cleaning is effective and cost efficient. Global food operators are increasingly aware of the benefit of an fully integrated hygiene approach and are implementing the complete programme including all requirements such as the following:

- **Commitment.** Everyone involved at the food premises must be committed to ensuring satisfactory standards of cleanliness are achieved. Requisite standards must be clearly defined and effectively communicated by management. Staff must be motivated, properly trained, supervised and controlled.
- **Training.** Sufficient numbers of adequately trained cleaning staff, properly supervised and supplied with appropriate materials and equipment, must be employed.
- **Comprehensive cleaning schedules.** Comprehensive, documented cleaning schedules should be established. Cleaning schedules are a communications link between management and staff and are necessary to ensure that equipment and premises are cleaned effectively and, if necessary, disinfected as frequently and as economically as possible.
- **Validation, verification and monitoring.** It is a food safety requirement that the performance of all cleans undertaken are validated by using the collected data that are relevant to the product safety and the processes and that revalidations are done if necessary. All cleaning operations should be monitored carefully to ensure that an area not only appears clean, but is also microbiologically clean. This can be done by the regular use of environmental swabbing or ATP bioluminescence testing. It is also useful during the cleaning validation process to assess the total energy used under controlled cleaning conditions. This is the baseline energy consumption to which any subsequent cost cuttings can be compared.
- **Fault finding.** A system for identifying problems must be established. Faults may be caused by poor management, administration deficiencies, unsatisfactory staff performance, inadequate training or unreasonable

expectation of individual performance. One approach is that standards are routinely monitored by management personnel not directly involved in cleaning operations and all findings are recorded and used to rectify faults and improve the effectiveness of cleaning.

One of the barriers to efficient cleaning operations is a lack of awareness, at all levels, that cleaning costs are an important issue. To make sustainable improvements, efficient cleaning, with its associated reductions in cleaning costs, needs to be part of the culture of the organisation. Once this is the case, staff will get in the habit of taking cost-conscious actions.

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